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Louise Blume

TOOLS OR RULES?

The utility and limitations of guidelines in Dutch hospitals



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Louise Blume

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Tools or rules?

The utility and limitations of guidelines in Dutch hospitals

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“A little knowledge is a dangerous thing. So is a lot.” — Alexander Pope

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Chapter 1

General introduction

Research shows that guideline adherence improves patient outcomes and has economic benefits [1-3]. In many countries including the Netherlands, society expects that high-quality care is delivered safely and that care providers and hospital boards comply with the applicable legislations [4]. In the Netherlands, hospital boards are held accountable for the implementation of guidelines in their organisations. Unfortunately, many of them are faced with the challenges of defining which requirements have to be met by whom and by when. This is in part due to the fast pace at which guidelines are changing, as well as the poor and unsystematic methods of communication about guidelines. Also, the high number of guidelines and the relationship between the board and staff play a major role in this difficult task of realising quality of care with shared responsibilities [5,6]. The following dialogue in Box 1.1 is an excerpt from an interview between the author and a board member of a Dutch hospital about guideline adherence in 2016 (Chapter 5). The board member's statements serve as an example of hospital board members' opinion on the importance of the implementation of clinical guidelines. What follows in this thesis is the description of a scientific pursuit for answers to the relevance, implementation, and surveillance of hospital guidelines within the Dutch context.

Author: Do you think that guideline compliance is desirable and necessary?

Hospital board member: I am pretty stubborn and I believe that it is necessary. I think that a professional must be equipped to do his/her job well. We (*hospital*) are not a bicycle or a car factory, it is not a set of components and at the end, there will be a car which must meet a certain quality standard. Cars are all the same, and the wheels are in the same place, and you can apply all kinds of quality standards. That is not our job. We do not have a set of components; we are dealing with unique human beings, with different pathologies, in different age phases, with different allergies, with different clinical conditions, you name it. You know what I mean. For this, you need a professional who justifies from a professional point of view what is needed for this patient. Guidelines should not impede with this, they should support it. And here, we are overdoing it with what is expected of doctors and nurses. And I am sure, of course,

that it no longer serves the goal it was intended to serve. It is fragmented; you see it in several aspects. A patient is a human, a functioning human being, not a collection of parts: it is not a heart and leg and a head, which you can approach separately. It is a human. A guideline often departs from different areas, whether it is for concentration of emergency care, or on the basis of legislation, and we sometimes get it totally wrong. What was the question?

Author: Do you think that guideline compliance is desirable and necessary?

Hospital board member: It is necessary and desirable to have guidelines. And you have to feel that you have room to deviate from it if well-argued. It must support your work, not be an obstacle or burden.

Box 1.1 - Excerpt from an interview between the author and a board member of a Dutch hospital

Background of the study

Guideline development Scientific knowledge is continuously growing, and it is estimated that there is a doubling of the global scientific (health and medical) output every nine years [7]. Guidelines are defined by the Institute of Medicine (IOM) as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” [8]. Guidelines and systematic reviews sum up the available scientific knowledge to support the decision-making processes in patient care. Initially, guidelines were targeted at caregivers and health care users, for whom they were meant as tools in the decision-making processes in daily practice. The first developed guidelines were mostly mono-disciplinary, focussing on a single profession. In these early versions, each professional’s responsibility was to understand which guidelines were applicable in their field.

The overall attitude towards guidelines as tools to achieve effective and efficient care is positive [9-11]. However, guidelines can still be improved, as they lack standardisation and face implementation barriers [10-11]. Several collaborative efforts on the national and international level have been undertaken to overcome the obstacles faced by guideline developers. Many countries have established guideline development programmes to

improve the quality of guidelines [12]. The Appraisal of Guidelines for Research and Evaluation (AGREE) has been developed in Europe. In 2010, the Dutch guideline developers created a “guideline for clinical guidelines” [13], which is tailored to the Dutch situation and complementary to the AGREE criteria. It was established to improve the quality of care in the Netherlands and was adopted by the National Health Care Institute, a public agency responsible for stimulating the development of quality standards and for public disclosure of quality information. Furthermore, a toolbox was developed to improve the quality and implementation of guidelines [14]. At the international level, collaboration was needed and, therefore, the Guideline International Network (G-I-N) was founded in 2002 to serve as a forum for the development, appraisal, and implementation of guidelines [15]. That these organisations are collectively engaging in guideline improvement efforts is an illustration of the fact that guideline development and its coordination has become more professional over the years.

Guideline implementation Even though scientific knowledge is summarised in guidelines, it is still difficult for hospitals and health care professionals to take all the given information into account [5]. A specific challenge lies in the implementation of guidelines for single diseases on patients with multimorbidity. Porter describes that the next challenge is to organise care delivery around medical conditions rather than single diseases, which is expected to result in care with higher value and improved experiences for patients. Guidelines should support “integrated practice units that encompass all the skills and services required for the full cycle of care for each medical condition, including common coexisting conditions and complications” [16]. A shift seems needed in the use of guidelines. Healthcare, as described in guidelines, is often for single diseases or interventions. Non-compliance is a common practice within hospital quality systems, as it is often accepted by health professionals, depending on experience, work conditions and patient characteristics [17]. Therefore, guidelines should consider the cumulative impact of treatment recommendations on people with several conditions, and allow comparison of relative benefits or risks [18]. Professionals need to be able to determine which guidelines are applicable for their patients at the specific point of time in care delivery. Some forms of care can be standardised (e.g. hip and cataract operations for relatively

healthy patients), whereas chronic care for patients with multimorbidity or care for frail elderly people is more complex, non-linear, and unpredictable. Especially for the latter, implementing and adhering to guidelines without considering the impact on the process of care is insufficient, as guidelines do not provide explicit guidance on treatment [19,20].

To improve the use of guidelines, a framework that includes features for guideline implementation was developed [21]. The framework suggests that guideline use can increase if guideline developers include these features. The domains of the features are usability, adaptability, validity, applicability, communicability, accommodation, implementation, and evaluation. Unfortunately, dissemination and awareness features are not included in the framework, although they are of great importance to promoting compliance [22]. The production and dissemination of guidelines are not sufficient to ensure that research evidence gets into practice [23]. This is a complex process and requires deeper investigation at each step of clinicians' awareness, agreement, adoption, and adherence to guidelines. Different types of interventions are needed to tackle the barriers, preferably with the stakeholders involved and over a longer period of time [24-26]. Hospital boards and doctors are more likely to use and implement the guidelines if they are intrinsically motivated and understand the potential benefit of working according to the current state of science [27]. It is important that their perspectives are taken into account and that the expectations concerning guideline adherence are realistic. For that to happen, Scott (2014) suggests that recommendations in guidelines need to focus on implementation challenges and be responsive to a changing environment [28].

Guidelines & Enforcement Traditionally, the primary target group for guidelines are professionals who use guidelines as a decision-making tool and for facilitating treatment choices in practice. However, in the Dutch healthcare system, other parties also have an interest in guidelines, such as insurance companies [29], the government and the Dutch Health Care Inspectorate (box 1.2) [30]. Insurance companies use signs of (non)compliance for contract negotiations [13, 14]. Non-compliance reported in the press impacts social expectations. Also, insufficient compliance is one of the issues about which patients file complaints with the Inspectorate [31]. The assumption is that increased compliance reduces damage caused to patients' health and increases public trust in health

care, and for this reason, the Inspectorate has focussed on promoting compliance with legislation, regulations, (professional) standards, guidelines, and norms [31,32]. If care providers fail to comply, the Inspectorate can take enforcement measures or initiate regulatory proceedings if the circumstances demand that immediate action should be taken. In other words, while guidelines were originally developed to support clinical decision-making, they are also (being) used as an enforcement tool of compliance in the Netherlands [4].

Role of the Dutch Health Care Inspectorate and the Role of the Board of Directors

The Quality of Health Facilities Act (KZi) was introduced in 1996. According to this law, the board of a hospital is responsible for the quality of care. Mainly on the basis of this law, the Dutch Health Care Inspectorate monitors the quality of care and addresses the hospital board in this responsibility. The Inspectorate translated this into holding the hospital boards in the Netherlands accountable for the implementation of guidelines since 2011. The Inspectorate is a governmental agency, responsible for regulating the quality of Dutch healthcare, focussing on promoting compliance with laws, rules, (professional) standards and clinical guidelines [32].

(The Quality of Health Facilities Act (KZi) was replaced by the Healthcare Quality, Complaints and Disputes Act (WKKGZ), which came into effect on 1 January 2016. The accountability for hospital boards continues unchanged.)

Box 1.2 - Role of the Dutch Health Care Inspectorate and the Role of the Board of Directors

With this development, the target group of potential guideline users was also broadened, and now also includes the board of directors, as they are explicitly responsible for monitoring the adherence to guidelines [33]. Moreover, guidelines are only a part of the whole regulatory burden that the board of directors of a hospital has to accommodate. Hospitals have to supply data on 1500 quality indicators for 45 diseases and interventions for public disclosure via the National Health Care Institute. These data are used by health insurers and for consumer information, e.g. on www.kiesBeter.nl. The influence of patient organisations on the quality of care is growing due to changes in Dutch health care policy.

Among other things, patient organisations develop standards and quality marks to empower patients and provide information so that patients know what to expect from hospital boards and professionals [44]. From the perspective of the hospital board, these standards and marks of quality are also part of the regulatory burden. So, apart from clinical guidelines, these external demands include standards, guidance, indicators, and non-clinical regulations, such as laws, rules, regulations, (volume and quality) norms from insurance companies, transparency obligations, health and safety requirements, letters and reports from the Inspectorate [35] (see Table 1.1 for definitions).

A Dutch hospital detected 1678 external demands in 2014 [36], and this amount expanded to 2400 external demands by 2017. This includes the retrieving of formerly issued guidelines and detecting newly published guidelines. In this total, the aforementioned quality indicators are counted on the level of indicator sets per disease or intervention (n=45). Figure 1.1 displays the external demands published between 2000 and 2016 (for more information: Chapter 2). These external demands can be found in the database l'artis of the hospital.

In conclusion Even though guideline development and implementation is an ongoing process, guidelines have increasingly been used as benchmarks for decision-making in health care practice and policy over the last two decades [20]. Guidelines are used in policy, and enforcement organisations base their decisions on guidelines [37, 38]. However, the amount of standards and guidelines in healthcare is large and increasing at a fast pace (Figure 1.1). Guidelines are published by an unidentified number of expert groups, and because the distribution is not systematic, awareness of the total volume of guidelines is limited (besides the database of the hospital).

Consequently, uncertainties can arise around the choice of guidelines to adhere to or not [39]. At the same time, users often know several guidelines that apply to them and the missing overview does not necessarily affect the ability to adhere to the guidelines they are aware of. In the Netherlands, no central body oversees the development and authorisation of guidelines. Professional communities (general practitioners, orthopaedists, surgeons, and so on) are self-responsible for the development and implementation of guidelines.

Table 1.1 - Definition

External demands	Clinical guidelines, including standards, guidance, indicators, and non-clinical regulations, such as laws, rules, regulations, (volume and quality) norms from insurance companies, transparency obligations, health and safety requirements and staff letters and reports from the Inspectorate [36].
Guidelines	In chapters 1, 2, 3, 5, 6, 7 and 8 the general term "guidelines" is used as pars pro toto for external demands. Of course, this is not the case if we use the specific term "clinical guidelines". Only in the survey study (Chapter 4) does the general term "guidelines" refer to clinical guidelines specifically, excluding other external demands. This was defined and specified as such in the survey.
Boards	Boards of directors and hospital boards are used interchangeably.
Use of guidelines	"Use" of guidelines refers to actively deciding how to handle a guideline. This implies that one has to be aware of a guideline [41]. Subsequently, one can choose to accept and apply the guideline, either with or without priority, or one can choose not to implement it. In this thesis, therefore, use of guidelines is not synonymous with implementation of or adherence to guidelines, and takes place between awareness and acceptance.
Implementation of guideline	Implementation of guidelines refers to the process of actively translating the recommendations in the guideline into practice by means of protocols, pathways, checklists, etc., in the setting of the hospital or clinical practice. This implies that the guideline is applicable, that one is able to implement it and that the user acts according to it. Frameworks to improve guideline implementation are available [21].
Adherence to guideline	Adherence has multiple meanings, such as adherence by patients to therapy and prescriptions [41] or adherence to guidelines by professionals. In this thesis, we use adherence in terms of behaviour and decision-making of professionals that is in accordance with the recommendations in the guideline. It is the extent to which recommendations are followed from a guideline or protocol [42].

The lack of central coordination and steering creates problems for the users (such as hospital board and management) of guidelines [40], that were not involved in the process

of the guideline development. We agree with Lavis (2012), that further investigation is needed into the division of labour in guideline and policy development [37].

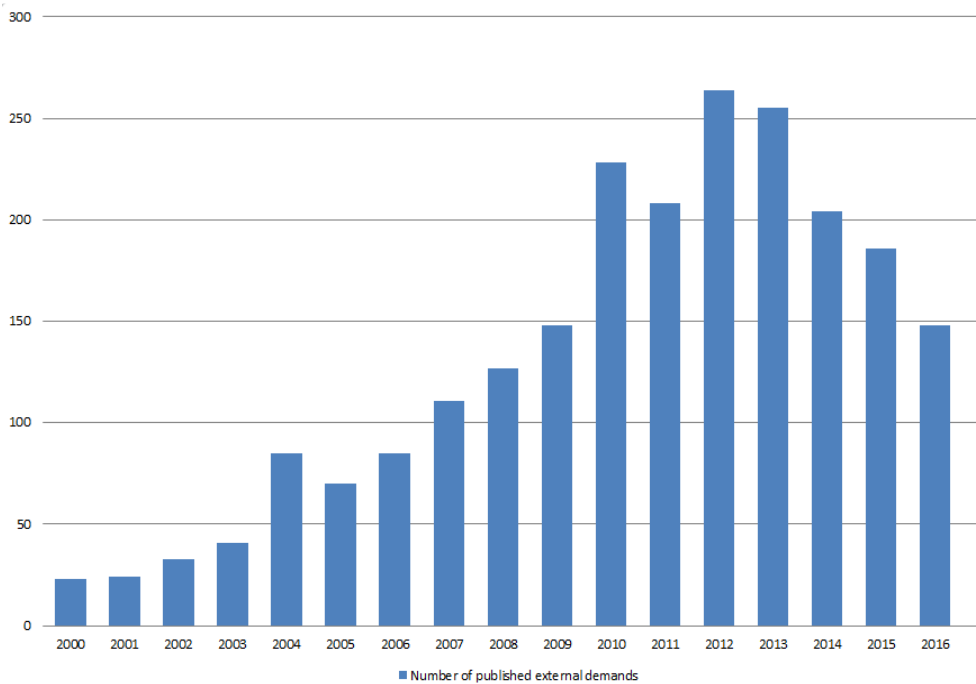


Figure 1.1 – Prevailing external demands by year of publication

In the course of our research, we discovered that external observers found it strange that in the Netherlands, hospital boards were held accountable for demands that they were unaware of. Reviewers asked us while reviewing our studies whether there is a discussion in the Netherlands about addressing the inefficiencies of the system through which the guidelines are created. We notice that the inefficiency has been recognised by society and there are ongoing conversations about how to ensure hospital boards are made aware of guidelines and how to limit their number [43-47]. Recognised professional bodies and scientific organisations can develop guidelines and demands, and they are used as “field standard” by the Inspectorate. This makes the guidelines and demands mandatory. For hospital boards, the responsibility for guideline implementation expanded from micro-level (professional is responsible) to mesolevel (hospital board is responsible). Medical

guidelines are meant to insure the delivery of a constant quality of care. For this, it seems necessary to check whether the guideline is actually used and if it achieves the intended effect.

Objective and research questions

The aim of this study was to acquire insights into how hospital boards realise compliance with guidelines and other external demands, and whether it is realistic to expect that this succeeds. A better understanding of the challenges in guideline implementation from the viewpoint of a hospital board may contribute to managing guidelines more efficiently in a hospital setting, developing more effective guideline implementation plans and, ultimately, improving patient care. This thesis thereby contributes to the body of knowledge in this domain. The specific research objectives of this thesis are as follows:

1. To assess how hospitals cope with clinical guidelines and other external demands.
2. To explore possible solutions that help hospital boards cope with external demands within their hospitals.

Thesis outline

In order to answer the research questions, different types of research designs were used. First, in a perspective study, we explored the Dutch context by investigating how one hospital board managed external demands after the hospital was placed under increased surveillance. Secondly, using a quantitative study, we investigated whether a risk-based prioritisation system helped other boards of directors cope with external demands, and how boards distribute their responsibilities in their hospitals. Finally, with the help of qualitative research, we investigated how hospital boards used guidelines in practice and how other hospital boards could learn from these experiences. The findings from this study concerning guidelines and hospital boards were presented in a focus group study to stakeholders, in order to identify possible solutions that could help cope with external demands within hospitals, focussing on the external context. In the discussion, we will

reflect on the findings, including the dilemmas we came across during the research. Table 1.2. summarises the design of the thesis.

Table 1.2 - Overview of this thesis

	Study	Research question	Design
1	How to manage external demands in hospitals – the case of Atrium MC	What is the feasibility of adhering to external demands and effective management by hospital executive boards of compliance with clinical guidelines?	Case Study
2	Optimal use of external demands in hospitals – a Delphi study from the Netherlands	Can a risk-based prioritisation system help hospitals cope with the pressures of external demands?	Delphi study
3	Guideline adherence: How do boards of directors deal with it? A survey in Dutch hospitals	Do Dutch hospitals experience challenges in complying with medical guidelines and what are possible difficulties and opportunities for improvement?	Quantitative (Survey)
4	What Hospitals Need to Know About Guidelines – A Mixed-Method Analysis of Guideline Implementation in Dutch Hospitals	How do these hospital boards ensure that guidelines are used in practice, and how do they minimise ‘leaks’ in handling compliance?	Mixed method Survey & Interviews
5	The inherent perils of (the multitude of) guidelines– a focus group study of stakeholders perceptions	More specifically, we looked at <ul style="list-style-type: none"> • what producers of norms and guidelines for hospital care can do to reduce the amount of guidelines/norms and improve the clarity and consistency? • what norm-enforcing institutions can do to focus and align priorities and reduce uncertainties for hospitals about what they are expected to comply with? • what hospital boards, managers and staff can do to successfully integrate norms and guidelines into hospital systems? 	Focus Group
6	Good intentions getting out of hand – is there a future for healthcare guidelines?	Good intentions getting out of hand – is there a future for healthcare guidelines?	Dilemmas

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Chapter 2

How to manage external demands in hospitals – the case of Atrium MC

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Abstract

In all modern healthcare systems, it is difficult for hospitals to keep pace with the increasing number of clinical guidelines. In the Netherlands, this poses a specific problem, as the national quality regulator holds hospital boards responsible for compliance with guidelines. We sought to address this problem by constructing a centralized database of guidelines. Due to the enormous number and the inter-relatedness of the guidelines, this task was larger and more complex than anticipated. This raises questions regarding the feasibility of adhering to external demands and concerning effective management by hospital executive boards of compliance with clinical guidelines.

A wake-up call

In February 2010, Atrium Medical Centre, a 700 bed teaching hospital with 200 medical specialists, providing an annual 27,000 admissions and 500,000 outpatient visits in the Netherlands, was placed under ‘enhanced surveillance’ by the Inspectie voor de gezondheidszorg (IGZ), the national regulator for healthcare quality. ‘Enhanced surveillance’ is an instrument that the IGZ imposes by means of an official warning. In this case, the IGZ threatened to close the operating theaters because the hospital did not adhere to a hygiene guideline and to the “air treatment plan in operation theaters”. Both guidelines were not deemed obligatory until that point, but were considered as non-mandatory guide- lines. The air treatment plan, in particular, had been developed by a committee of experts and was intended to serve as a consensus document rather than an enforceable regulation. Nevertheless, the official warning placed upon the Atrium Medical Centre resulted in higher alertness to clinical guidelines and other external demands (e.g. consensus documents or legal requirements) in Atrium Medical Centre. The executive board of the hospital wanted to be better prepared by developing a structure to coordinate, respond to and control clinical external demands in the future.

In the Netherlands, as in other Western healthcare systems, hospitals are important healthcare suppliers. Therefore, regulation of hospital quality is important. However, in a recent essay, Greenhalgh et al. state that ‘the number of clinical guidelines is now both unmanageable and unfathomable’.¹ In this essay, we shall describe how the national quality regulator triggered an effort to gain control of this problem. The national quality regulator holds hospital executive boards accountable for compliance with clinical guidelines and other external demands and is entitled to enforce this policy with penalty fees and forced closings of services. We aim to describe how the Atrium Medical Centre has tried to cope with this responsibility and to discuss what other hospitals can learn from this approach.

Background

Prior to 2011, it was common practice that the IGZ visited hospitals annually to examine and discuss overall medical policy and to carry out in-depth investigations with respect to safety incidents. In 2011, the IGZ announced that they would focus more strictly on promoting and if necessary, enforcing “compliance with legislation, (professional) standards and guidelines”, hereafter referred to as “external demands”.² In this essay, the term “external demands” comprises anything a hospital is obliged to implement by external parties responding to broader social, political and contextual factors. These include laws, rules, (professional) standards, guidelines, codes, instructions, guidance, as well as quality indicator sets that hospitals have to measure and report on publicly.

After declaring their new policy on compliance, the IGZ did not further specify standards and guidelines with which hospitals must comply, nor did it give a concrete definition of the professional bodies whose guidelines are considered applicable in the hospital setting. Quality metrics form an exception: the IGZ explains in detail which quality indicators should be measured, and where, when and how indicator scores should be submitted. However, with regards to compliance of standards and guidelines, they are far less specific. Topics for inspection visits are announced on a yearly basis, but the universe from which they are selected is broad and not defined a priori. Therefore, a basic condition for a pro-active compliance management is lacking. This is where the action of Atrium Medical Centre started.

After making inquiries among several colleagues in the ninety university, teaching and general hospitals in the Netherlands and their sector associations, the leadership of Atrium Medical Center concluded that the problem faced by hospital boards is that there is no overview of applicable external demands. Apart from that, the dissemination of relevant guidelines to a variety of hospital professionals, with different areas of expertise, is not well-organized. This lack of oversight and dissemination contributes to the problem of overload³ and lack of adherence, which is prevalent in Dutch hospitals as in other countries.^{4,5} Problems encountered by too many guidelines have been observed before,⁶ but no solution has been offered. While colleagues from Germany did not experience enforcement measures, they are challenged by the same knowledge-gap related to

external demands in their systems and acknowledge that too many demands are made upon hospitals.

Atrium medical centre's response to the challenge

The official warning given to Atrium Medical Centre motivated the hospital board to initiate a thorough study and inventory of external demands and guidelines so they could form a pro-active approach to responding to such regulation.⁶ The Quality and Safety Department started collecting guidelines in spring 2011. The first priority was to identify medical, nursing and governance guidelines and then later expanding the scope to include all external demands, including IT, hygiene, pharmacy, finance, etc. At present, the data collection is still ongoing.

The initial aim was to collect all external demands, split them into individual requirements, then eliminate redundancy and finally deliver them to the professionals affiliated with Atrium Medical Centre – a policy we had derived from good dissemination practices in chemical and construction industries. However, due to the large amount of external demands we encountered, this appeared to be too time-consuming, so a new aim was set, which was twofold: firstly, to gather all external demands existing within the Dutch hospital sector in a database and secondly, to make external demands easily accessible to management and professionals. The database is called l'artis, which is inspired by the Latin term "lege artis". It means working according to the rules of art. To fill the database, we systematically searched for directories and websites containing external demands related to Dutch hospitals and newsletters for information on other external demands.

Each external demand was added to the database, including the title of the external demand, concerned discipline and specialties and publication year. Due to the diverse structure of the different external demands, it was challenging to fill the database consistently. For example, it is often unclear whether the date in the guideline refers to the publishing date or the date of validation. In most guidelines (estimated 90%), an expiry date is missing. Often it is unclear, as to whether the external demand is evidence-based or consensus-based. In several cases, it even is uncertain whether relevant professional

bodies have authorized the document at all. L'artis is now functions as a library and central reference point for external demands within Atrium Medical Centre for two areas: first, to elaborate protocols and practices to be in line with the external demands, and second, to serve as a reference point for internal audits. To improve access for professionals, the Quality and Safety Department started using l'artis to establish which external demand belongs to which specialty. The database is searchable by title, specialty and publication year of the external demand.

As of January the 1st 2014, 1678 external demands had been gathered. Currently, up to 20 newly published titles are entered per month. The database makes it possible to link external demands to specific groups of professionals. When evaluating compliance to specific patient care processes, multiple applicable guidelines are found: for instance, in the surgical pathway, not only the guidelines for safe perioperative care and procedure-specific surgical guidelines apply, but also rules and guidelines for anesthesiology, and record-keeping apply.

Requirements may contradict each other or be unsafe when combined, as was learned from a devastating case study of a ward in 2008. An elderly patient was fixated in bed to prevent doing herself harm, while also using an anti-decubitus mattress to prevent pressure ulcers. Both preventive measures were applied to conform to the respective guidelines, but the patient strangled herself as the mattress allowed for more movement than intended.

The goal is now to attract external cooperation in filling the database. The time investment required to maintain this database is enormous. Partnership with other hospitals would ease this burden, while helping meet an urgent need to recognize and address external demands.

Discussion

The initiative can be considered successful in the sense that the Atrium Medical Centre now knows what external demands are imposed on hospitals. The existing external demands for Dutch hospitals can be found in l'artis, which is used as central reference

point in the Atrium Medical Centre. However, it remains difficult to keep the database updated, as the publishing of external demands is high paced and unstructured and notifications when new guidelines are published are limited. As a practice, guidelines and external demands are not periodically published at certain time intervals, so a substantive permanent search activity is necessary. Compiling a database is only a first step and will not be sufficient in supporting medical specialists and hospital management to guide their implementation activities. Other barriers to implementation include time needed to implement a single external demand, specialties needing to stay apprised of guidelines outside their own specialty that may still apply, and difficulty coordinating, selecting, and prioritizing external demands.

However, there is little literature that describes the scope of the problem, as implementation studies usually focus on the implementation of one single guideline at a time. As a hospital, we are responsible for the compliance with a multitude of guidelines and while the Atrium Medical Centre is aware of their external demands, it is unclear whether it is at all feasible to meet the 1600 external demands. Guidelines were intended to support the commitment towards better quality health services, and to reach standardization by decreasing variation.⁷ While necessary, the purpose needs to be clear as some external demands are merely intended as guidance for professionals, while others are mandatory and thus provide a basis for supervision and enforcement.

The creation of the database was a reaction to a problem that is not specific to Dutch hospitals. However, the role of the IGZ, which is to expand the responsibility of hospital boards and professionals to comply to all external demands and maintain quality and safety of care has triggered our endeavor to find a way to cope.

At present, five other Dutch hospitals are investigating the possibilities in working together on l'artis. We are committed to introducing an appraisal of the relevance of external demands for hospital management based on risks, and to fuel the debate about the problem of multiple and conflicting external demands placed on hospitals by organizing invitational conferences and discussions with the IGZ, and other stakeholders.

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Chapter 3

Optimal use of external demands in hospitals – a Delphi study from the Netherlands

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Abstract

Background

Regulatory authorities focus on promoting compliance of hospitals with a variety of external demands. Due to the amount of these external demands, hospitals might prioritise to cope with the external demands. In this study, we explore to what extent a risk-based prioritisation system developed by one Dutch hospital, is applicable in other hospitals as well. The specific research question was: can a risk-based prioritization system help hospitals cope with the pressures of external demands?

Methods

We conducted a Delphi study, containing three rounds with seven quality and safety managers. All participants were experienced in coping with external demands in Dutch hospitals in general and their own hospital specifically. These experts were granted access to a sample selection of a database containing about 1500 external demands. Prior to the Delphi study, a baseline measurement was carried out, where all participants answered open-ended questions aimed at identifying existing practices, possible challenges concerning external demands and to prepare the survey for the group Delphi study.

Results

We identified a high level of consensus during our Delphi research. The experts agreed that at present, Dutch hospitals do not cope with external demands systematically. The participants agreed that the database and the risk-based prioritisation system are useful tools to cope with the amount of external demands and indicated that they would also like to use these tools themselves in the future.

Conclusions

In this study, the participants agreed that the database and the risk-based prioritisation system are both applicable and useful tools to cope with the amount of external demands. Further research addressing the use of the risk-based-priority system for specific subsets of external demand is also needed.

Background

Nowadays, hospitals have to deal with many external demands. These external demands are specific requirements and expectations that healthcare institutions must adhere to in order to obtain or renew licensure to practice. A large amount of external demands are clinical guidelines, which were originally developed to synthesize scientific evidence, professional experience and patient preferences. They were meant to promote the use of new knowledge and achieve standardisation to decrease variation in the procedures [1]. Moreover, they were intended to support decision-making by professionals and patients in the doctor's office or at the bedside. However, clinical guidelines have taken on significantly more meaning today in hospitals and other healthcare institutions.

The use of clinical guidelines, or specific aspects of those guidelines, became obligatory in many countries [2, 3]. Research around the world has been devoted to investigate the implementation of, and adherence to, guidelines in various healthcare organisations. Failure to implement guidelines has been reported in the literature for instance in the UK for fragility fracture prevention guidelines [4] and in Turkey, North America, Jordan and Tanzania [5–8]. In these studies, different causes for non-adherence were identified, such as a weak evidence base for recommendations and the lack of standardized communication pathways. A few studies specifically identified the great number of guidelines as one of the reasons for non-adherence. In a Canadian study, nonadherence to guidelines in the intensive care unit was examined. One of the conclusions was that there were too many guidelines to adhere to [9]. The same was mentioned in a study conducted in 2010 in the United States for nutrition guidelines [6]. Another Canadian study showed that there were gaps between the recommendations in several critical care nutrition guidelines and the reality at the bedside [10].

Strikingly, nearly all of these studies analysed the adherence to just one guideline or a set of guidelines around one topic. Similarly, models and theories about hospitals adherence to guidelines, such as Graham et al's knowledge-to-action cycle [11], focused on specific topics and specific guidelines, and not on the overarching question of how to apply the total volume of clinical guidelines. In our study, we focus on the problem of hospital compliance with all applicable external demands, as this defines the regulatory

burden the Governing Board has to accommodate. These include clinical guidelines but non-clinical regulations as well, such as standards, guidance, indicators, laws, rules, regulations, (volume and quality) norms from insurance companies, letters and reports from the inspectorate. In the Dutch context, all of this is mainly enforced by the Dutch Health Care Inspectorate (IGZ) [12].

Full hospital compliance with all of the mandatory external demands is a widespread problem and is not unique to the Netherlands. However, we use the Netherlands as an empirical illustration of the issue. A brief description of the healthcare system and hospitals in the Netherlands is provided below for a better understanding of the Dutch context.

Healthcare system and hospitals in the Netherlands

Dutch general hospitals are privately owned and funded through a premium-based insurance system [13]. The quality of healthcare delivery in the Netherlands is regulated by the IGZ, which functions under the auspices of the Ministry of Health, Welfare and Sport. For its regulatory tasks, the Inspectorate promotes compliance with external demands [12, 14], by using various enforcement measures ranging from the provision of recommendations, imposing fines, up to compliance orders. The conditions under which these measures are operationalized are governed by two laws - the Quality Act and Medicines Act.

Regulation by the IGZ has intensified over the last decade for all external demands and in its wake, the compliance with external demands became mandatory in 2011. This meant that all care services had to be provided in accordance with these demands [12], resulting in new problems for hospital management. This is not only a Dutch phenomenon, as many governments around the world are consolidating the regulation of medical professionals and institutions [15]. This study took place in multi-specialty facilities. The majority of Dutch hospitals - just like in other Western countries - are multi-specialty facilities that combine acute and chronic care as well as diagnosis and treatment in an increasingly multidisciplinary environment. This phenomenon might contribute to the amount of different external demands that a hospital has to comply with. In the

Netherlands, the development of guidelines is not coordinated centrally [14]. It is, therefore, difficult for hospitals to have a complete overview of all external demands.

Many institutions, medical speciality organisations, professional groups, researchers, healthcare providers, insurers and patient organisations are actively engaged in the development of guidelines for clinical practice. The state only provides a legislative framework for external demands while the details are worked out by professionals and providers [13]. If any group engaged in guideline development fails to develop a field norm or standard reference, the IGZ has the mandate to develop such a norm itself. This particular approach to healthcare system governance is based on negotiations and consensus-seeking between the state, professional bodies, healthcare providers, patients and insurers – i.e., between the state and the ‘societal partners’ in healthcare [13]. However, there is no mandated list of parties that are considered to have development authority with regard to clinical guidelines or other external demands on hospitals.

For the quality of care and hospital performance to be consistently organised in Dutch hospitals, the collaboration between the Executive Board and the medical specialists is needed and this is formally regulated in Admission Agreements [16]. However, this traditional way of collaboration is shifting. In the Dutch Quality Act of 1996, the Governing Board has been named as the legal entity responsible and accountable for the quality of care. This central role for the “Governing Board” is underpinned in the so-called Governance Code of the Trade Association of Care and the IGZ [12]. It is questioned whether the Admission Agreements provide hospital Executive Boards with sufficient legal options to assume their responsibilities regarding quality and safety [17].

Problem statement and research questions

In a recent study, healthcare guideline developers stated that guidelines aid the decision-making process for physicians and patients [18]. However, the sheer amount of external demands threatens to render them impractical for daily use. This poses the question how objective prioritisation can take place; a question highly relevant both to both hospitals and regulators.

In order to stay up-to-date with external demands and to demonstrate to the IGZ and the outside world that the Governing Board is in control, the Zuyderland Medical Centrum (Zuyderland MC), a large teaching hospital in which two of the authors worked during the study (LHKB and NJHWW), created a database (bearing the name l'artis). This database lists all external demands Dutch hospitals have to adhere to in an effort to make them structurally available within the hospital, and to facilitate prioritisation [19]. Departing from the risk-based prioritization system that has been developed in Zuyderland MC, we aim to investigate whether other Dutch hospitals are subject to similar problems and whether the risk-based prioritisation system developed in Zuyderland MC could help them in coping with external demands, too. In this sense, this is a feasibility study analysing whether a solution developed in one hospital could be implemented in other hospitals and deliver useful results. For the purpose of this study, we formulated the following research question: 'Can a risk-based prioritisation system help hospitals cope with the pressures of external demands?' In addition, we developed the following sub-questions:

1. Do the participating hospitals experience similar challenges in complying with external demands?
2. Can managers from other hospitals use the risk-based prioritisation system that Zuyderland MC developed and how useful will they find it?
3. Can they assess the external demands which were collected and disseminated by Zuyderland MC in the same way?

Methods

In the Netherlands, there are currently more than 1500 external demands used to guide and monitor the performance of hospitals [19]. In an attempt to conform to these regulations, Zuyderland MC introduced several regulatory procedures. One of these procedures entailed the compilation of all the external demands into the l'artis database and development of a risk-based prioritization system. In this system, the Governing Board can directly determine that an external demand has a high priority by giving the score 1000. Other external demands can also receive a risk-score from seven staff members of the quality and safety department, after which it the risk-score is discussed

with the management and afterwards adopted by the Governing Board. Every risk score is based on the sum of five different risk descriptions, namely: sanctions enforced by the IGZ, risks for patients, financial risks, reputational risks and risks related to the quality of care. Each external demand receives a risk score between zero and 1000. Scores above 150 indicate serious risks in the five areas. External demands with a risk score above 150 are implemented with priority and the progress of is monitored quarterly. A protocol and scoring table exists to apply the risk-based system, but for our study, a simplified protocol was developed, since only one individual instead of a group of people, registered the scores.

This research used a Delphi study to test whether this risk-based prioritisation system is suitable for other hospitals as well. The participating hospitals were not randomly selected, as explained in step 1, and the guidelines were partially randomly selected, as explained in step 4. The following six research steps were completed during this research.

Study population (step 1)

The eight hospitals of the Association of Tertiary Medical Teaching Hospitals (STZ) in the southern region of the Netherlands, as well as a general hospital in the region, were invited to test the risk-based prioritization system and the database. The group consisted of one academic hospital, one small hospital, and seven non-academic teaching hospitals. The experts were quality and safety managers, responsible for handling external demands in their own hospital. Two hospitals did not participate in this study due to time constraints, therefore seven hospitals agreed to participate in this study. The response rate of the seven participants was 100 % for all six research steps.

Research instruction protocol (step 2)

To guide participants in using the Zuyderland MC risk assessment method, an instruction protocol including six steps for the risk-based prioritisation system was developed by the author LHKb. The protocol was tested on comprehensibility, logic and language by four Zuyderland MC employees, none of whom had been previously involved in risk-based prioritisation: a secretary, a policy employee, the Quality and Safety department manager

and a policy employee of the Governing Board. The protocol was adjusted and retested by the policy employee of the board.

Baseline measurement (step 3)

To identify existing practices and possible challenges concerning external demands and to prepare the survey for the group Delphi study, a baseline measurement was carried out. The experts received seven open-ended questions by email, with the purpose of discovering if and how hospitals deal with external demands at present.

Applying the risk-based prioritisation system (step 4)

The research instruction protocol guided participants from a broad set of external demands to those of highest priority, using the five risk descriptions, namely sanctions enforced by the IGZ, risks for patients, financial risks, reputational risks and risks related to the quality of care. The participants received a sample selection of 250 of the 1515 external demands in the l'artis database. To ensure that sufficient discussion would arise and to avoid that too few priorities would be left after the random selection, we decided to select all 72 external demands that had previously been assessed as a priority in the Quarterly report by Zuyderland MC. The remaining 178 were randomly selected in the database of external demands. The aim of the sample selection was to reflect the reality on a smaller scale and the task was to apply the research instruction.

Firstly, the participants entered the database and individually screened 250 external demands to select a maximum of 40 external demands for further assessment. Only the 40 demands that the participants selected for their hospital, had to be scored by them using the five risk descriptions.

The group Delphi study (step 5)

In step five, the Delphi technique was applied; this is a commonly used method to gather information from an expert panel. The Delphi method was chosen as it facilitates the discovery of strengths and weaknesses of a new system. It helps to seek answers to improve the understanding of developments, forecast, problems, opportunities and

solutions [20]. The unique feature of the original Delphi technique is the repeated questioning, whereby the interim results from earlier rounds are presented together with new questions. The face-to-face communication is replaced by distant communication and characterized by anonymity. The original procedure can easily take 2 to 9 months [21].

To reduce the length of the period needed for the study, the Delphi-members agreed to participate in a group Delphi study on the 27th of January 2014. The difference in this approach compared to the original Delphi technique is that experts are physically present in the same location and that the different rounds of the Delphi study can be carried out in sequence. Therefore, the duration of the Delphi study can be reduced to a single day [21]. The literature gives no indication that the shorter duration affects the results. It does affect the anonymity, which is not given during a group Delphi study. The main communication during a group Delphi study is based on questionnaires so that tight structuring beforehand is necessary and the statements of the questionnaires need to be prepared largely in advance [21].

To test the logic, comprehension and language of the statements, five think aloud tests were carried out with non-participants of the Delphi study, after the statements for round one were developed. A think aloud test is a form of cognitive testing in which participants verbalize their thoughts as they move through the questionnaire with the aim to identify and subsequently improve the items that are perceived as confusing [22]. The feedback was processed after each test before the next person was subjected to the think aloud test. After all test were carried out, the Delphi method was applied.

Data collection (step 6)

The participants were gathered in one location, at Zuyderland MC, but placed separately in different rooms, where three rounds of Delphi research were conducted. The SurveyMonkey's tool was used for each round [23]. The research was carried out in Dutch. The statements of round 1 were entered beforehand while the statements of round 2 and 3 were added during the Delphi execution day. These latter statements were based on the results of round 1 and 2. The research team used the break between each session to perform an analysis, and to develop new statements for the next session. Some examples

of the statements that were developed included 'It is important that we as a hospital meet external demands', 'It is important that hospitals know which mandatory external demands for critical processes they have implemented in their hospital' and 'The riskbased prioritisation system can be useful for hospitals to manage the external demands'.

In order to reach consensus and to compare the results, participants responded to assumptions using a two-item scale ('agree' and 'disagree'). A 'no opinion' option was not included, but text boxes for comments were provided where applicable (in about half of the statements). The responses were calculated and defined as achieving consensus (≥ 80 % agreement) or nonconsensus (< 80 % agreement). Participants rated their agreement with the statements in each round. In the case of non-consensus or numerous comments, the statements were refined for the following round [21]. Bar charts representing the distribution of responses were generated using the SurveyMonkey software. Panel response rates remained 100 % across all rounds. At the end of the day, a group discussion took place.

Independence

Two of the authors worked in Zuyderland MC (LHKB and NJHWW) and the third one (DMJD) is both a Professor at Tilburg University and the head of the quality programme of the National Health Care Institute, a government agency. To enhance independence of this study, an advisory committee supervised this research. The developer of the risk-based scoring system (NJHWW) did not participate in the development of the Delphi questions and in the analysis of the results. He did participate in the Delphi study itself. Also, a draft article was reviewed by a IGZ advisor.

Ethics Statement

Under the Dutch law, a Delphi study in which healthcare professionals and managers participate is not subject to ethical approval. Nevertheless, prior to commencing this study, the authors checked at the Medical Ethical Committee Atrium-Orbis-Zuyd whether ethical approval was needed and it was confirmed that it was not needed for this study.

Results

Results Baseline Measurement

Participants declared that they did not have an overview of all existing external demands, especially not when it came to the clinical guidelines developed by professional associations. They indicated that they prioritised the implementation of mandatory external demands on critical processes. External demands high on the agenda of the IGZ were listed by most hospitals. The majority of participants stated that it was not clear who is responsible for the distribution and implementation of external demands within their hospital. According to them, the current arrangement was too decentralised and unknown. Participants stated that there is a need for more structure concerning the use of external demands.

Results Risk-Based Prioritisation System

After the application of the research instruction protocol, the seven participants logged their selections and risk scores in a spreadsheet and delivered it to the researcher. One external demand was chosen by all seven participants and it contained quality indicators for infection prevention in hospitals. It was published by the Society for Hygiene and Infection prevention in Healthcare (VHIG) and the Dutch Society for Medical Microbiology (NVMM). Three external demands were selected by six hospitals and three external demands were selected by five hospitals (Additional file 1). The selected external demands focus on infection prevention, quality standards, Dutch standards (NEN norm) and the safety management systems. Half of the external demands, 125, were not prioritised by a single hospital.

Approximately 50% of the selected external demands are directly related to the IGZ. One hospital selected 12 external demands related to the IGZ and another selected 25. Half of the selected external demands were applicable to the hospital as a whole, not merely to a specific department or specialism. Two external demands were labelled as top priority of the Governing Board by four hospitals. Both are external demands focused on safety management systems.

Results Delphi

Seven experts participated during the group Delphi Study. Six of the seven experts were on the same location and one expert participated from another location. They all fully completed the three rounds of the survey individually. At the end of the day, a discussion took place on the statements of non-consensus of the third Delphi round. The participant at the other location did not participate in that discussion. Overall, the participants achieved consensus on most statements. The consensus of the three Delphi rounds is displayed in table 3.1.

The analysis of the first round results led to a number of more specific new statements in round 2. In the second round, 19 questions were formulated to provide in-depth details for the results of round 1 and a further 17 were added. Round three focused on items that needed clarification to achieve final consensus. Eleven statements were presented, all of which were completed. In total, full consensus was obtained for the essential aspects.

Table 3.1 - Distribution of consensus among the statements in three Delphi rounds

Round	Statements	Consensus	No Consensus	Open questions
1	35	28	4	3
2	36	22	11	3
3	11	5	5	1

Consensus

Participants agreed that the infrastructure for external demands in Dutch hospitals needs to be arranged more effectively. An overview is needed for compliance management, to prioritise external demands and to be proactive. They stated that it is important to monitor external demands regularly to stay informed about national developments and concurred that a central external demand officer should be instated in each hospital.

According to the participants, governing boards currently cannot know the degree of compliance within their own hospital, since it is unclear where new and existing guidelines for medical specialists are collected and how the professionals use guidelines. They agreed that one can monitor whether the everyday practice is in accordance by structuring the

internal dissemination and the implementation of external demands. Participants established that the registration of the implementation status is desirable within their hospitals and that the database could facilitate this.

According to the participants, an external demand receives more attention in hospitals when enforcement measures by the regulator (IGZ) are in place. Nevertheless, they also stated that it is not always clear which external demand will be actively enforced next. Participants noted that unexpected visits by the regulator are useful in consolidating the importance of these demands. Participants estimated that it is impossible to implement everything due to the amount of external demands and they feel that more focus is necessary. They noted that the standards for judging and deciding of the IGZ should be set up thoroughly and, in their opinion, this had not always been the case in the past. The majority of the participants did not recognise the IGZ-enforced issues as the most important ones for quality and safety, and thus questioned whether implementation of these external demands was the most effective contribution to risk reduction and quality improvement in their hospital.

During the discussion it became clear that the perceived role of the IGZ is influential, however, enforcement by the IGZ provokes reactive policies from hospitals when it comes to setting priorities. Participants stated that they would like to be proactive in their management of locally foreseen risks but feel that, because of IGZ policy, they are often forced to be reactive as they are behind on compliance. Participants also chose whether or not to implement external demands and declared that it is important to capture these substantiated choices. They saw the necessity for other bodies, such as the Dutch Hospital Association, National Health Care Institute, Royal Dutch Medical Association, and the Knowledge Institute of Medical Specialists, to understand the need to choose which external demands should be implemented with priority. All of the participants claimed that the Dutch Association of Hospitals should help hospitals to communicate these choices to the IGZ.

Scoring risks

Consensus was reached that the database and the risk-based prioritisation system of Zuyderland MC was applicable and useful for other hospitals to manage external demands. Participants indicated that their prioritisation of external demands was influenced by those of the IGZ as well as of other enforcers, ensuring that these topics were on the list.

Participants recommended that more than one person should perform the prioritisation in order to enhance reliability and that in addition to staff employees, some physicians and other clinical experts should be involved. The five risk descriptions formed an adequate basis to prioritise the external demands based on risks. According to 100% of the participants, a new element called 'actuality' should be added to get a better picture of the risk. The descriptions 'scope' and 'publisher' of external demands could also be added as to assess risks according to 86% of the participants.

Participants also stated that nationwide agreements are needed concerning the production, the dissemination and the validation of external demands applicable within the Dutch hospital sector. Attention should be paid to the design of external demands, for example by making it mandatory to use state-of-the-art methods for clinical guideline development. Until this happens, they agreed that working on the database together was useful and also recommended regular exchange between them to discuss high priorities. They concurred that this exchange will support the choices participants make concerning external demands and it could reduce the risk of missing significant external demands. All participants agreed that the Governing Board should be able to add priorities next to the risk-based prioritisation system and that the board should bear ultimate responsibility for ensuring compliance while the medical specialists share the responsibility for managing external demands.

Non-consensus

The participants could not agree on whether it was too complicated to communicate choices of implementing external demands to patients, public, insurers and other bodies. The majority of the participants believed that if properly substantiated, the IGZ, public or

insurers may show an understanding if hospitals decided not to implement certain external demands. It was emphasized that this understanding would depend on the external demand and the communication strategy used.

The participants disagreed on whether the date of publication affected their prioritisation. Also, during round 1 the participants disagreed on the description 'financial risk' and 'reputation risks'. During the Delphi rounds, discussion arose on the necessity to assess the external demands and whether specific background knowledge is needed. It was apparent in the final discussion that one must scan the external demand text, i.e. to the health problem it addresses, to assess the risk involved in non-adherence, but not read it in detail, as many external demands have hundreds of pages elaborating on technical and procedural solutions.

Discussion

Our main research question was: 'Can a risk-based prioritisation system help hospitals cope with the pressures of external demands?'. Overall, the results of this study show that Dutch hospitals do experience challenges in complying with external demands and that a risk-based prioritisation system could help them to cope with this pressure. The power of the database and the risk-based scoring system lies in the local embedding, as they provide the Governing Board with the possibility to act proactively. However, effects of other possible implementation procedures, e.g. one where medical specialists take a proactive role, were not included in this research. Further research is needed on the tension between a top-down approach by the Governing Board, and the bottom-up approach in which medical specialists tackle specific risks and challenges in their local practice.

The study shows that the participating hospitals experience great difficulties in coping with a large amount of external demands, which is in line with what Carthey et al (2011) stated for healthcare compliance in the UK [24]. As mentioned in the introduction, guidelines were originally developed to summarize existing scientific evidence to reach standardisation [1] and to support decisions for professionals and patients in the doctor's office and at the bedside. Some parts of guidelines are advisory and others mandatory

[18]. Half of the problem of non-compliance is that guidelines are non-applicable, not known about, out of date or unworkable [25]. This seems to be neglected when guidelines and other external demands are given a mandatory status. If the expectations were defined more precisely, external demands can be addressed more efficiently and compliance could be improved.

This study also shows that the infrastructure for meeting external demands in Dutch hospitals needs to be arranged more effectively. As pointed out in the introduction, the Governing Board is named as the legal entity that is responsible and accountable for the quality of care. Even though Governing Boards and managers are aware of many external demands, it is hardly possible to know and monitor all of them. The overview, and therefore awareness, is missing [26].

The findings of this study show that the database and the risk-based scoring system are useful to deal with external demands on a local level. However, the tension between the local approach and the national approach can arise, as it is expected that Governing Boards comply instead of prioritise. The supervision of the IGZ will still take place and enhancements may follow. Whether prioritisation is desirable on a national level was not a part of this study and it was also not addressed whether priorities can better be balanced on local or national level. A national debate about these issues is desirable and is currently being initiated by the authors.

Another finding from our study was the substitution effect of enforcement. According to the participants, the external demands received more attention in hospitals if enforcement measures by the regulator were at hand. This in itself is in accordance with the aim of external enforcement [12]. Activities from IGZ and other regulators, even unexpected visits, were perceived as useful support by participants to achieve compliance, if they addressed the external demands which had priority on local level. However, in areas which were not chosen as local priority, activities of regulators urge Governing Boards to re-prioritise to the detriment of local needs. This substitution might decrease the impact of compliance management on actual quality improvement and risk containment. It would be interesting to conduct further research on the balance between

the internal supervision, where the local risks are close and the external supervision, based on national level considerations.

The study shows that working on the database jointly with other hospitals could be useful and that regular exchange between hospitals is desirable to discuss high priorities and national developments. Hospitals can share the same source of information about external demands and use similar strategies for prioritising and coping with demands. At the moment, four hospitals have agreed to continue the work on the database and the risk-based prioritisation system together. The feasibility and success of implementing this system may improve by involving the target group during development and distribution. This contributes to efficiency and capacity building and might mutually facilitate improvement of risk-assessment as hospitals can compare their scores. Further research that addresses the use of the risk-based-priority system for clearly defined subsets of external demand is needed.

Internationally, this study is also interesting. However, regulators around the world need to ask themselves to what extent enforcement measures are beneficial in ensuring compliance, when does it just pull health professionals away from other, equally important tasks. Greenhalgh et al (2014) stated that to “equate ‘quality’ in clinical care with strict adherence to guidelines or protocols, however robust these rules may be, is to overlook the evidence on the more sophisticated process of advanced expertise” (p.3) [27]. Enforcement can lead to undesirable side effects, Robben states, such as strategic behaviour, manipulation and fraud [28]. For countries, where central coordination of the development of external demands is missing, the problem is probably similar to the Dutch situation. These countries could also benefit from the results of this study, as a risk-based priority system might be a possible solution for them, too. Further research is needed on this topic.

Strengths

Some of the strengths of this study include the full participation of all responders (no drop out) through the study. Also, the Delphi questions from round 1 were prepared critically, and 15 different testers contributed their expertise to the statements. Furthermore, the

participants examined a large set of external demands for the risk-based prioritisation system to make the results representative for the entire set. Finally, the findings from our study may be useful for other Dutch hospitals and for hospitals across countries, as the study did not deal with the specific content of the external demands but challenged the question from a governance perspective.

Limitations

Before interpreting our findings, several limitations should be considered. One being, that Delphi studies generate expert consensus and therefore rank low as scientific evidence. Another limitation is that we included quality and safety managers with a positive attitude towards external demands and that one person carried out the risk-based prioritisation system per hospital. A further limitation is that the medical teaching hospitals from the south of the Netherlands work together on various fields and this might influence the strong agreement on many issues.

The existence of the database adds value to hospitals; however, it can still be improved. To ensure that experts can assess and prioritise thoroughly, it is desired to add a summary of each external demand to the database. Debating the findings of this study during a round table session with various stakeholders from in and around hospitals may be useful since these barriers should be addressed nationwide.

Conclusions

At present, Dutch hospitals are not structurally dealing with external demands. During the Delphi study the participants agreed that the database and the risk-based prioritisation system of Zuyderland MC are both applicable and useful tools to cope with the amount of external demands, and that they would like to use these tools in the future. At the moment, four hospitals have agreed to work on the database and the risk-based prioritisation system together.

Additional file 1: Selected external demands

Top seven of the most selected external demands with Date of Publication, External Demand, and Number of hospitals that selected the external demand, Total score and sort external demand.

Date of Publication	External Demand (Dutch)	External Demand (English)	Number of Hospitals selecting the external demand	Total score by each Hospital
2012-11	Kwaliteitsrichtlijn voor Infectiepreventie in Ziekenhuizen versie 2.0	Quality indicators for infection prevention in hospitals	7	201 220 1000 175 275 195 185
2012-06	Normering Chirurgische Behandelingen 3.0	Standards Surgical Treatments	6	151 226 1000 185 47 150
2011-10	NEN 7510 Informatiebeveiliging in de zorg	Dutch standards (NEN norm)	6	1000 1000 1000 96 111 96
2012-08	Kwaliteitsindicatoren 2013 Basisset ziekenhuizen	Quality indicators by the IGZ	6	1000 1000 1000 186 105 96
2010	Richtlijn het preoperatieve traject	Surgical Guideline	5	1000 1000 1000 250 260
2005	Beheersplan Luchtbehandeling voor de Operatieafdeling	Air treatment plan in operation theatres	5	1000 1000 111 80 171
2011	NTA 8009 Veiligheid managementsysteem voor ziekenhuizen en instellingen	Dutch Technical Agreement, Safety management systems	5	1000 1000 350 226 260

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Chapter 4

Guideline adherence: How do boards of directors deal with it? A survey in Dutch hospitals

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Abstract

Background

Adherence to guidelines is often low, as multiple barriers exist for guideline implementation. To tackle the implementation problem, awareness of the existence of guidelines is necessary for the health care process and setting as a whole.

Purpose

Despite the importance of guidelines adherence, problems have been reported from hospitals in achieving this. This study gives insight into how boards of directors of general and specialist hospitals arrange the responsibilities for guideline adherence within their organisation, how they deal with guidelines for medical specialists and what opportunities exist for improvement.

Methods

A survey was sent to 116 Dutch hospitals in 2015. 39 responses were included in the study for further analysis (net response rate of 36%). All data other than the open questions were analysed in SPSS using descriptives to answer the research question.

Results

The findings demonstrated that the distribution of responsibility concerning guideline implementation is problematic. The boards of directors used a variety of information sources to keep informed about the status of implementation of the guidelines for medical specialists, mostly through medical specialists' peer reviews (visits) and internal audits. The study revealed several opportunities for improvements, for example, that a national database is necessary with all up-to-date guidelines, whereby changes and news are distributed directly to hospitals and other stakeholders.

Conclusion

This paper offers recommendations for a thoughtful shift in distribution of responsibility, as in a more desired situation the ultimate responsibility of the board of directors would decrease and the responsibility of the medical specialists would increase.

Introduction

Preventable harm is the third most frequent cause of patient death around the world and has partly been associated with the inadequate adherence to hospital guidelines by health care providers [1]. Consensus-based and evidence-based guidelines for diseases are continuously being developed to improve the quality of care. However, adherence to these guidelines has been reportedly low, due to the presence of multiple barriers hindering implementation [2]. The awareness of the existence of guidelines to ensure safe care has been identified as one of those barriers [1, 3]. We were interested in knowing whether boards of directors in Dutch hospitals are aware of the full scope of medical guidelines they are responsible and accountable for and wanted to find out how they act on them.

Up until now, problems with implementation have predominantly been investigated by examining one guideline at a time, per disease or case. Implementation strategies have been tested and retested to achieve better results, however, without taking overall contexts into account [4]. To tackle the implementation problem as a whole, awareness of the existence of guidelines is necessary, not only for those on a single topic or disease but also for the health care process and setting as a whole. More attention needs to be directed to changing systems that support guideline implementation rather than those that focus on the behaviour of individual clinicians [5]. This study, therefore, investigates what the current boards of directors' perspectives are on the governance structure concerning guideline adherence.

Pronovost (2013) suggests that guideline developers ought to shift their focus away from relying on the performances of individual clinicians towards systems that can support guideline implementation. This line of thinking aligns with the General System Theory that suggests problems can effectively be solved by using systems or a systems approach [6, 7]. According to this theory it is argued that when seeking a solution to a problem, it is important to consider all parts of an organisation or context in order to avoid repetition of the same activity or intervention. This is because it is impossible to resolve every problem at the local level alone or as isolated units. A hospital is a complex organisational system and consists of various activities with different levels of inputs, outputs and operational

processes. Therefore, it is logical to assume that if hospital management considers all medical guidelines (input) as an entity rather than isolated units, then hospital management should be able to implement guidelines (processing) more efficiently in order to achieve good patient outcome (output) (Figure 4.1). In our study, we will approach the hospital management as a system, which has inputs, processes and outputs.

As guidelines are continuously being (re-) designed and developed, hospitals constantly need to adjust their operational processes in order to be able to adhere to them. In the nursing and medical profession, specialisation is an autonomous process, which is a result of the expansion of medical knowledge. Consequently, guideline development takes place within highly specialised professional subgroups. During implementation in a hospital, several guidelines have to be taken into account simultaneously, as the real situation is more complex than the fragmented specialisation in one guideline. Clinicians have to deal with patients suffering from multiple morbidities. At the same time, clinicians and managers have to translate requirements and processes described in a variety of guidelines into coherent rules, protocols and regulations. We want to know how boards arrange responsibilities for adherence within their organisation.

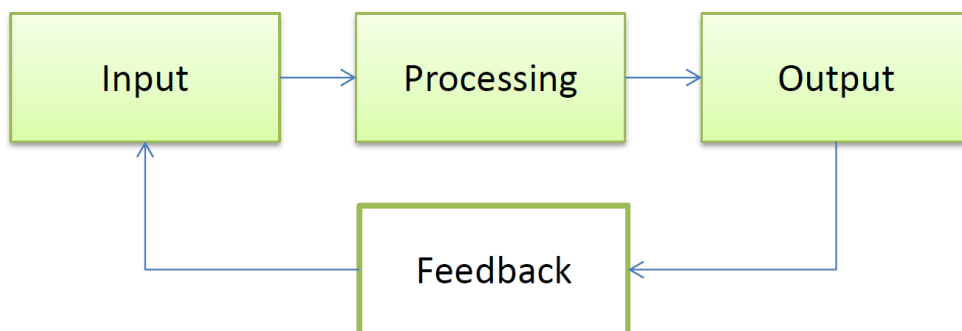


Figure 4.1 - Hospital Management as a system

The adoption and correct implementation of all quality standards within a hospital is the responsibility of the board of directors. Clinicians, being specialists within their own field and their respective scientific associations (are expected to) develop guidelines for their

own disciplines and are also expected to adhere to them. We want to know how the board keeps informed about the implementation status of guidelines.

Dutch hospital board members are our object of study and we focus on medical guidelines within hospitals. This study examines how boards of directors of general and specialised hospitals in the Netherlands deal with guidelines for medical specialists, how they arrange responsibilities for adherence within their organisation, and what challenges or problems they experience in organising adherence. The insights from this research could be used to improve guideline usage in hospitals and policies regulating guideline adoption and implementation in hospitals. This study addresses the following research question and sub-questions: How do boards of directors of Dutch hospitals deal with guideline adherence?

1. Do boards of director's experience problems in adherence with medical guidelines?
2. What is the governance structure, i.e. how do boards:
 - a. arrange responsibilities for adherence within their organisation?
 - b. keep informed about the implementation status?
3. Is there a relation between the governance structure and the problems that boards experience?
4. What are the perceived opportunities for improvement?

Methods

Study Design and Participants

We collected both quantitative and qualitative data to investigate the challenges Dutch hospitals face with regard to guideline adherence. The study was conducted in the Netherlands between March and June 2015. All hospital board members of the Dutch Hospital Association (NVZ), comprising a total of 116 health-care representatives, were invited to participate. The member organisations are either general, specialist or teaching hospitals. University Medical Centres were not invited.

Survey

The questions for this survey were developed based on an earlier Delphi study [8], using statements on which all participants agreed and using statements on which no one agreed. Questions were developed to assess the board of directors' understanding of guidelines and their responsibility for compliance. The questions were organised into four main categories. The first category focused on the problems experienced by the boards of directors, where we assessed the feasibility of guideline adherence, and the problems experienced by boards of directors on the distribution of responsibilities. The second category concerned questions to assess the governance structure. Questions were asked about the responsibilities for guideline adherence and how boards keep informed about the implementation status of guidelines. The third category included questions about the relation between the governance structure and the problems that boards experience. In the fourth category, board members were asked what the opportunities are for improvement.

The survey was pretested through five think aloud tests by non-participants of the study working in a hospital to test the usability. During a think aloud test participants are asked to talk aloud whatever thoughts come to their mind as they move through the survey [9]. The aim is to detect design issues and improve the items that are observed as difficult. The outcome from a think aloud test was processed after each test before the following test took place.

After the test, the boards of directors received a digital questionnaire which consisted of 51 questions, using the web-based tool SurveyMonkey. Seven questions were open questions, nine questions were closed-ended questions with ordered response choices, two questions were dichotomous questions and 33 questions were Likert scale questions. Ten of the multiple choice questions had the possibility for entering comments in an open field, which was not compulsory.

Data Collection

The 116 contact persons for members of the NVZ received a digital invitation including the link to the survey. After four weeks, a reminder was sent. The participants were given the

opportunity to enter their hospital name and their occupation for the analysis of the researchers. In total 56 responses were received, representing 54 Dutch hospitals, a response rate of 46%. Participants who filled out less than 50% of the questions were excluded from the analysis (N=15), including empty submitted surveys (N=2). After exclusion, 39 responses remained, representing 39 Dutch hospitals, which were included in the study for further analysis, representing a net response rate of 36%. For three questions, the open comment fields were coded and added to the original possible answers, as many responses corresponded to one of the previously given categories, together with an explanation. It seems as if participants wanted to specify why they chose one category, that's why we assume they often used the open comment field.

Analysis

First, we prepared the dataset for the 39 responses with SPSS and recoded the ordinal variables into dummy variables. All questions other than the open questions were analysed in SPSS using descriptives to explore differences between the distributions of responsibilities. If necessary, the open comments fields were coded and added to the original possible answers. Secondly, the chi-square was used to test whether two variables answers are related to each other, and we used it to answer whether the boards of directors experience problems in adherence to guidelines and what their governance structure is ($p < 0.05$). For the first three research questions, the results of the experiences of boards of directors regarding responsibility were examined in contrast to other results of the survey (Tables 4.1, 4.2 and 4.3). Analyses were performed using IBM SPSS Statistics 21 and Excel.

Results

Experiencing Problems

The majority of the boards of directors reported that they find it problematic to establish who is ultimately responsible for guideline adherence for medical specialists.

Table 4.1 - Feasibility of guideline adherence versus experiencing problems with distribution of responsibility

It is feasible for hospitals to adhere to all guidelines for medical specialists	Distribution of responsibility		Total n (%)
	Not problematic n (%)	Problematic n (%)	
Agree	8 (53%)	7 (47%)	15 (100%)
Disagree	7 (33%)	14 (67%)	21 (100%)
Total (Chi-square: 1.44, p-value 0.23)	15 (42%)	21 (58%)	36 (100%)

Table 4.1 compares the feasibility of a hospital's capability to assure medical specialists' guideline adherence in settings where problems are perceived versus those where none are experienced. The chi-square test showed (1.44, p-value 0.23) that no statistically significant association was found between the feasibility of hospitals ensuring medical specialists' adherence to all guidelines and the experience of problems with the distribution of responsibility.

Governance Structure

Two items were investigated in this section, focussing on the governance structure, i.e. how do boards a. arrange responsibilities for adherence within their organisation and b. how do they keep informed about the implementations status.

Responsibilities for Adherence

The distribution of the responsibilities for discipline-specific and non-discipline-specific guidelines varied. The perceived problems were not clearly linked to the governance structure designed to allocate the responsibility for the implementation of guidelines (see Table 4.2).

Table 4.2 - Reported distribution of responsibility versus experiencing problems with distribution of responsibility

	Distribution of responsibility		Total n (%)
	Not problematic n (%)	Problematic n (%)	
Experience with establishing responsibility – Total	16 (41%)	23 (59%)	39 (100%)
Responsible for discipline-specific guidelines Q9			
Medical specialists, professional associations from relevant speciality	5 (38%)	8 (62%)	13 (100%)
Medical speciality society	2 (100%)	0 (0%)	2 (100%)
Board of directors	9 (43%)	12 (57%)	21 (100%)
Otherwise, namely	0 (38%)	3 (100%)	3 (100%)
Responsible for non-discipline-specific guidelines Q10			
Medical specialists, professional associations from relevant speciality	1 (50%)	1 (50%)	2 (50%)
Medical speciality society	2 (50%)	2 (50%)	4 (100%)
Board of directors	12 (39%)	19 (61%)	31 (100%)
Otherwise, namely	1 (50%)	1 (50%)	2 (100%)

In the majority of cases, the board of directors reported being responsible for guideline adherence. This was the case in 21 out of 39 hospitals in cases of discipline-specific guidelines and in 31 out of 39 hospitals for non-discipline-specific guidelines. However, in 13 hospitals, medical specialists were reported to be responsible for adherence to discipline-specific guidelines in their own area of professional expertise.

In hospitals, where the responsibility was reported to lie with the board of directors, the number of respondents that experienced problems was slightly overrepresented. This was both the case for discipline-specific guidelines as well as for non-discipline-specific guidelines. More than half of the participants stated that the structure in their hospital is decentralised to ensure that guidelines for medical specialists are known by those responsible for their implementation (not in table). The ultimate responsibility is recorded in written form in 59% of the hospitals.

As we already pointed out, 59% (n=23) of the boards of directors experience problems in the establishment of responsibility. We asked these 23 participants to specify what they find problematic in the establishment of responsibility for guideline adherence in an open field. The participants stated that it is almost impossible to verify adherence. Numerous (n=10) participants reported that problems occur because they lack an overview of the guidelines. They stated that the number of guidelines was too large to be manageable for a hospital and one stated that their medical specialists report that it is not possible to be up-to-date in regard to all guidelines. Participants stated that part of the problem is that information about new or updated guidelines is not collected centrally within a hospital but decentralised.

Keeping Informed about the Implementation Status

The participants stated that they used a variety of information sources to keep informed about the status of implementation of the guidelines for medical specialists, mostly through medical specialists' peer reviews (visits) and internal audits (see Table 4.3).

Based on the results of Table 4.3, we can see that in general there is no correlation between the way boards of directors inform themselves about the implementation status of guidelines and the degree to which they experience problems establishing responsibility for guideline adherence. However, boards of directors who rely on checks of adherence by external bodies such as the Inspectorate for Healthcare, IGZ, (n=29) reported problems more frequently in the distribution of responsibility for guideline implementation (Chi-square= 4.66, $p = 0.03$). There was a significant relationship between the board of directors who consulted the departments/speciality concerning the status of guideline adherence regularly (annually/quarterly) and the degree to which they experienced problems with distribution of responsibility (Chi-square = 3.813, $p = 0.0508$).

In an open question, participants were asked what steps are taken if progress on guideline implementation is insufficient. They stated that they brainstorm with the internal stakeholders to put systems in place, demand accountability, address the insufficiency, and then support them in working towards improvements. Enforcement, sanctions, or supervision were reported as possible steps by a few participants.

Table 4.3 - The information source (multi-response question) of the board of directors on guideline implementation versus experiencing problems with distribution of responsibility

	Distribution of responsibility			
Experiences with establishing responsibility:	Not problematic n (%)	Problematic n (%)	Total n (%)	Chi-square (P-value)
How does the board of directors inform itself on the status of implementation of guidelines for medical specialists? (multiple answers possible)				
Through reports of peer reviews conducted by the medical specialists	14 (39%)	22 (61%)	36 (100%)	0.883 (0.34)
Through internal audits	12 (36%)	21 (64%)	33 (100%)	1.927 (0.16)
Through checks on medical specialists' adherence to guidelines by external bodies such as the Inspectorate for Healthcare	9 (31%)	20 (69%)	29 (100%)	4.666 (0.03)
The board of directors consults regularly (annually/quarterly) with the departments/speciality concerning the status of guideline adherence	12 (55%)	10 (45%)	22 (100%)	3.813 (0.05)
The departments/speciality report on the status of implementation of guidelines that have high priority within our hospital	4 (36%)	7 (64%)	11 (100%)	0.138 (0.71)
The departments/speciality report on the status of implementation of all guidelines for medical specialists	1 (25%)	3 (75%)	4 (100%)	0.473 (0.49)
Otherwise, namely	2 (13%)	13 (87%)	15 (100%)	7.726 (0.005)
Total	16 (41%)	23 (59%)	39 (100%)	

Is there a relation between the governance structure and the problems that boards experience?

Table 4.4 compares the board of directors' experiences with the implementation of guidelines to their level of awareness about the stages of implementation for medical specialists. Twenty participants stated that the hospital board is informed of the guidelines for medical specialists that have priority within their hospital, but 14 (70%) of those did experience problems in establishing the responsibility for guideline adherence. Five hospitals expressed through the open comments field that the awareness is limited, and one respondent pointed out: 'The number of guidelines is so large that I do not dare to say that we are aware of all guidelines'.

Table 4.4 - Familiar with status of implementation versus experiencing problems with distribution of responsibility

	Distribution of responsibility		
Experience with establishing responsibility:	Not problematic n (%)	Problematic n (%)	Total n (%)
To what extent is the board of directors informed about the status of implementation of guidelines for medical specialists? It is informed of the status of implementation of:			
All guidelines	6 (55%)	5 (45%)	11 (100%)
The guidelines that have priority within our hospital	6 (30%)	14 (70%)	20 (100%)
Not one guideline	0 (0%)	0 (0%)	0 (0%)
Otherwise, namely	4 (50%)	4 (50%)	8 (100%)
Total	16 (41%)	23 (59%)	39 (100%)

Opportunities for Improvement

Firstly, the participants received Likert scale questions on the opportunities for improvement around guidelines. They agreed (95%) that a clean-up action is needed to determine which guidelines are invalid (e.g. due to new improved guidelines, the guideline is no longer feasible or does not contribute to better quality of care). Also, they agreed (92%) that hospitals should be able to defer the implementation of clinical guidelines beyond a predefined deadline, assuming that they provide a good justification. Furthermore, participants agreed (87%) that hospital representatives should be involved

in the development of guidelines to encourage guideline developers to pay attention to the preconditions for implementation. Seventy percent agreed that a large number of guidelines for medical specialists has a negative impact on their intrinsic motivation for their profession. More than two-thirds agreed that guidelines receive more attention if they are strictly enforced. More than 60% stated that the Inspectorate does not permit a hospital to decide that certain guidelines for medical specialists are not implemented, even if well argued (from the perspective of the hospital).

Secondly, the participants were asked in an open comment field about the main opportunities for improvements that they see. Of 82% of the participants who responded to the questions on possible improvements, the majority stated that the main opportunity to improve the situation is a central national database/portal with all up-to-date guidelines, whereby changes and news are distributed directly to hospitals and other stakeholders. They said that an overview is necessary to ensure that the collection of guidelines is well organised, to avoid duplication, to reduce the number of guidelines and to prioritise based on the risks for quality of care. Guidelines should include certain criteria such as distinct organisational and financial conditions, user-friendly layout, criteria for the expiry of guidelines and the availability of a summary of each guideline. It should be clearly stated which parts are mandatory and which parts are optional. Participants revealed that a distinction is necessary between (parts of) guidelines that aim to provide guidance for professionals and (parts of) guidelines that are used for enforcement for which hospital boards are held accountable. One participant stressed that it is important that major national stakeholders restrict themselves to the mandatory guidelines to avoid different institutions having dissimilar requirements regarding medical specialists' guidelines. Some participants stated that it is an opportunity to focus on the organisational impact in relation to risk management between the number of guidelines and the impact and workability in practice. A clear division of responsibilities for medical specialists and the board of directors should be regulated by the guidelines themselves.

Discussion

In this research, we examined how Dutch boards of directors of hospitals dealt with guideline adherence. Overall, our study revealed a valuable insight into how boards of directors of general and specialist hospitals arrange the responsibilities for guideline adherence within their organisation, how they deal with guidelines for medical specialists and what opportunities exist for improvement.

Responsibilities for Adherence and Experience of Problems

Boards of directors of hospitals have the responsibility for the adoption of all quality standards. Therefore, it is imperative that they are able to oversee all of the guidelines, ensure adherence to the guidelines by all specialities, and also strive that for a smooth transition within and across the different units within their hospital organisation. This is particularly important for them to be able to understand the dynamics and also implement the guidelines optimally within the hospital settings. This process fits within the logic of the General System Theory.

Boards experience challenges in arranging responsibilities for adherence within their organisation. As mentioned in the Introduction, it is a new challenge for boards of directors to be responsible for guideline adherence for medical specialists. A large number (79%) of the participants agreed that the board of directors was ultimately responsible for non-discipline-specific guidelines compared to discipline-specific guidelines (56%). The participants stated that in an ideal situation the ultimate responsibility of the board of directors would decrease and the responsibility of the medical specialists would increase. This contradicts with the prevailing views in Dutch politics and the current policies on hospital governance. The division of responsibilities between medical specialists and management is an important issue in the occurrence of incidents in health care. It is still unclear how to monitor supervision when it comes to aspects of the responsibility of all stakeholders [10].

The results show that there is a gap between the desired and the actual situation; 97% of the participants stated that it is important that hospitals adhere to the guidelines for medical specialists while only 42% stated that this is feasible. To allow adherence to work

according to the General Systems Theory, it is essential that a hospital receives all input, agrees with it and is able to adhere to it. At present, only 28% of the boards of directors are informed of the status of implementation of all guidelines. Hospitals require a systematic input of guidelines for hospitals, where all applicable medical guidelines are taken into account.

In this study, we see that the problems of boards of directors are diverse: it is impossible to verify adherence, an overview of guidelines is missing, and too many guidelines exist. It is interesting to see that while nearly everyone thought that it was important to adhere to guidelines, half of them agreed that it was not feasible. For future research, we need to widen our focus from hospitals to the health care system at large, since the hospital is a part of the health care system, which is a larger system. This study shows that hospitals are influenced by Inspectorate enforcement: participants used Inspectorate enforcement and the results to guarantee adherence to guidelines for medical specialists. Guidelines with enforcement receive more attention within a hospital. According to other studies, we need to be careful that the emphasis on legislation, quantifiable information and enforcement does not evoke counteraction [11, 12]. Enforcement leads to top-down control and leaves little room for bottom-up arrangements, which might provide better fitting answers to health problems. Ruan, Ma, Vo and Chiravuri (2015) state that guidelines should be used as guidance rather than enforcement standards because wrong guideline use may result in patient harm [13].

How Boards of Directors of Hospitals in the Netherlands Deal with Guidelines for Medical Specialists

The study has shown that boards of directors are rather passive in disseminating and securing guideline adherence for medical specialists. Participants stated that they organised and oversaw adherence separately in the local units (decentralised) and that physicians, together with their professional groups, have a major role. When questioned about how they keep informed about implementation, the boards of directors mostly referred to external and internal audits and to their protocols. Here, the boards of directors actually wait for something to happen (reactive) rather than getting things done

before they are asked for it (proactive), as they rely on checks rather than previously embedded pathways to adherence. The goal of the boards of directors seems to be: as much decentralisation as possible. The question is then under what circumstances does this lead to insufficiency? What has to be centrally coordinated? How can boards of directors organise decentralised adherence while still being able to bear their responsibility? A possible theoretical approach could be shared or distributed leadership which is useful in complex social problems with different stakeholders. The interests of the patient are central in distributed leadership, and the focus is on learning and negotiating instead of decision-making and implementation [14].

The participants were also asked about what steps were taken if progress on guideline implementation was insufficient. They stated that they brainstormed with the internal stakeholders to put systems in place, demand accountability, address the insufficiency, and then support them in working towards improvements. Boards of directors revealed that questions about adherence were tackled collectively and that they searched for possible solutions together. The question is whether this fits into the realm of control of the boards of directors and whether they tackled it this way due to the lack of other options. Only a few participants mentioned enforcement, sanctions or supervision as a possible step for non-adherence, which is interesting as this is a way the boards of directors could take their responsibility. In this research, 22 participants stated that they consult the departments regularly concerning the status of guideline adherence, and twelve of those do not experience problems in the establishment of responsibilities. The boards of directors are living with a decentralised solution, where trust seems to be a key element in the relationship between the board and the medical specialists. In this research, we did not study how boards arrange insights into how departments organise and execute adherence. Further research would be interesting to investigate under what circumstances centralisation is necessary and what boards need to be justified in their confidence in trusting to the decentralised adherence solution. It would also be interesting to find out how much hospital infrastructure is devoted to guideline implementation and what the resource implications would be.

Implementation of Guidelines for Medical Specialists

Participants reported differently on the process of implementation and its status. Eleven boards stated that they know the implementation status of all guidelines, and five of those experience problems in establishing responsibilities. Six boards of directors knew the implementation status of all guidelines and experience no problems in responsibility establishment. This is not a high number if we take into account that the board is ultimately responsible for guidelines. However, it is a high number if we take the answers from the open comments field into account. Here, boards of directors reported that they can hardly live up to this responsibility on their own as the medical specialists and other stakeholders have a professional responsibility to work according to the guidelines of their profession. Also, five boards of directors expressed that awareness is limited and one respondent pointed out: 'The number of guidelines is so large that I do not dare to say that we are aware of all guidelines'.

Results from another study revealed that we can learn from Sweden. The recommendations in their national guidelines are linked to a degree of priority which is used for decision-making and prioritisation. In the Netherlands, we could use a similar system in the national overview to set priorities [15]. What is also interesting is that Sweden appoints healthcare decision makers as the primary target group of guideline users as the guidelines offer support for control and management. Their approach adds a substantially different element in the overall system, as priorities are introduced as an option for adherence management. 'The objective is to promote the efficient use of healthcare resources, as well as their allocation on the basis of need and their management on the basis of systematic and transparent priorities' [16]. It could be good to gain experience of the risk-based prioritisation approach in the Netherlands [8].

Perceived Opportunities for Improvement

Our analysis on the manner in which hospitals are working on guideline adherence indicates that at this time, no adequate solution has been found to systematically ensure that a hospital operates in accordance with medical guidelines. Considering the problems experienced, hospitals cannot resolve the question as it is now manifested. We need to

zoom out to create more distance to understand what is going on. At present, stakeholders work within their own systems: guideline developers in their system of producing and disseminating guidelines, the Inspectorate in their system of surveillance, and hospitals in their system of implementation.

What we need is networking between these systems with a helicopter focus – metaphorically speaking a helicopter needs to be launched. Where do the inputs for a hospital come from and what is the purpose of the sub-system that produces them? Such an analysis would include guideline development and enforcement as it is part of the wider quality system. An analysis would allow a possible reassessment of the goals and purposes of the quality system as a whole and its sub-systems. We are thus opening a new perspective to the debate. We would like to bring the debate forward, by including the surrounding systems of a hospital and we plan to deploy it in further research activities.

Limitations

Before interpreting our findings, several limitations should be considered. With this study, we were able to gather necessary information from the boards of directors. However, out of 116 hospitals, only 39 completed the survey. Although we have no reason to assume selection bias, we are unable to check to which extent these boards are representative of all Dutch hospital boards. The respondents had different roles in the hospital organisations. Members of boards of directors were asked to complete the survey, but also, other staff members filled in the survey which could lead to bias. For three questions, the open comments fields were coded and added to the original possible answers. Despite numerous pre-tests, the respondents could not place their answer in the existing categories. A possible bias lies in self-reporting as participants may not do what they say they do.

Conclusion

This paper has shown that boards of directors experience difficulties in the responsibility of medical guideline implementation. It offers recommendations for a thoughtful shift in the distribution of responsibility, as in a more desired situation the ultimate responsibility

of the board of directors would decrease and the responsibility of the medical specialists would increase. If the board of directors is ultimately responsible they should be supported by a systematic input of all relevant and available guidelines to be able to organise adherence management.

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Chapter 5

What Hospitals Need to Know About Guidelines – A Mixed-Method Analysis of Guideline Implementation in Dutch Hospitals

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Abstract

Rationale, aims and objectives

This study provides insight into how Dutch hospitals ensure that guidelines are used in practice and identifies what key messages other hospitals can learn from existing practices. We examine current practices in handling compliance and, therefore, focus on hospitals that reported that they do not experience problems in the implementation of guidelines.

Method

A survey of Dutch hospital boards and 9 semistructured interviews were conducted with a purposive sample of 3 hospitals. Interviews were held with 3 representatives of each hospital, specifically, with a member of the board of directors, a member of the executive medical staff, and the manager of the quality and safety department.

Results

Hospitals find guidelines necessary and useful. Hospitals have the power to improve implementation if boards of directors and medical staff are committed, intrinsically motivated, cooperate with each other, and use guidelines pragmatically. Even then, they prioritise guidelines, as resources are scarce. Despite their good work, all hospitals in this study appeared to struggle to adhere to guidelines.

Conclusions

If hospitals experience problems with guideline implementation, they tend to focus more on external expectations, leading to defensive behaviour. Hospitals that do not experience implementation problems focus more on integrating guidelines into their own policies.

Introduction

Clinical guidelines were, among other things, developed to reduce unwanted variations in health care practice [1]. Even though this goal is still legitimate, a gap exists between scientific evidence and clinical practice, as too much evidence is translated into numerous guidelines [2-6]. The number of guidelines makes it difficult for healthcare practitioners and hospitals to be aware of every existing guideline and to comply with them [7,8]. In 2011, the state regulator (Dutch Health Care Inspectorate) announced a stricter protocol of guideline enforcement [9]. The Inspectorate holds boards of directors responsible for guideline implementation. Thus, the Inspectorate ensures that hospital boards offer responsible care. Dutch hospitals are aware of the excessive volume of guidelines and claim that the healthcare sector needs a significant reduction in guidelines and regulations to mitigate the high administrative burden [10]. As a result, the Dutch government is attempting to decrease regulations in the healthcare sector by reducing the number and improving the quality of guidelines by 2017 [10]. However, it is unlikely that the number of guidelines in the Dutch healthcare sector will decrease within the next few years, because different stakeholders continuously update existing guidelines and develop new ones, focusing for instance on multimorbidity, shared decision-making, and decision aids within guidelines [8]. Most hospital boards in the Netherlands perceive problems with the implementation of guidelines, although a few of them stated in an earlier study that they did not experience such problems [11]. In order to learn from these potentially good examples, we set out to explore how these specific hospitals ensure that guidelines are used in practice and which factors contribute to this.

Theory

Our theoretical model for understanding the problem at hand is the 'leaky evidence pipeline' concept of Glasziou and Haynes [12], which is based on the awareness-adherence model of the steps to clinical guideline compliance [13] (Figure 5.1). The pipeline consists of seven stages, ranging from awareness to patient outcome, and focuses on how the use of evidence can be enhanced for physicians. The model shows that leakage occurs at each stage, which reduces the potential impact on patient outcomes.

Lack of awareness is the first leakage which needs to be stopped to increase the chance of a guideline’s implementation. If an organisation or person is aware of a guideline, they must subsequently decide whether they accept the guideline or not. They then need to check the applicability and whether they can implement it or not. The final step is to act according to the guideline. In practice, these steps are not easy to accomplish and, therefore, leakage occurs. This study focuses on how hospitals prevent leakage and uses the pipeline to discover and describe how the hospitals participating in this research study implemented guidelines. The focus is on hospital boards and (medical) staff, but not on the role of patients. Therefore, the steps ‘agree’ and ‘adhere’ were not addressed, as these components of the pipeline can only be studied in the context of professional-patient interactions.

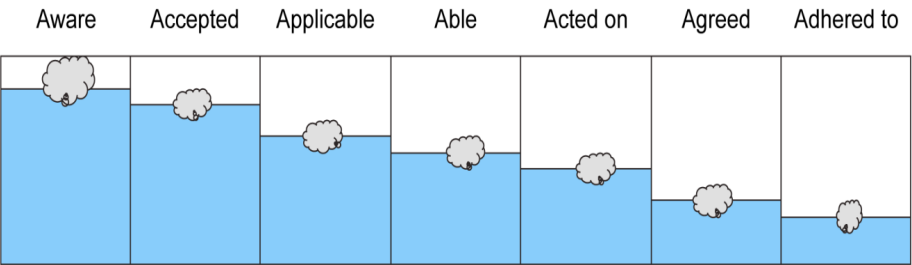


Figure 5.1 – Guideline to practice - the leaky pipeline from awareness to adherence [12]

Using the findings from an earlier study [11] – in which we identified a few hospitals that claimed to experience no guideline implementation problems – in this research, we set out to explore guideline implementation in three of those hospitals. The research questions are: how do these hospitals ensure that guidelines are used in practice and how do they minimise ‘leaks’ in handling compliance? Our aim is to identify what other hospitals can learn from their good practices.

Method

The Standards for Reporting Qualitative Research (SRQR) checklist was used to ensure that the necessary information is provided [14]. A mixed-methods approach was chosen for this study, because gathering information through different methods not only strengthens the research design, but it also enhances the ability to reliably interpret the outcome data [15]. The data input was both quantitative (derived from a survey [11]) and qualitative (interviews) in nature.

In 2015, as part of a larger study about hospital boards of directors' responsibility for quality of care [11,16,17], we conducted a survey to learn how hospitals established responsibilities in their organisation and how supervisory activities of the Inspectorate influenced this. A total of 116 hospitals in the Netherlands were invited to participate in this survey. Thirty-nine hospitals completed the questionnaire. General results and the full details of the methodology are described elsewhere [11]. Here, we present additional survey findings that have not been published previously and we use the survey data to select positive deviant hospitals for in-depth interviews. Positive deviant participants were purposely sampled, comprising a subset of 13 out of 39 respondents who agreed with at least two out of three of the following statements about their hospital:

1. The board of directors is aware of the status of implementation of all guidelines for medical specialists (11 of 39 respondents agreed) [11].
2. The board of directors does not experience problems in the establishment of responsibility for compliance with guidelines for medical specialists (14 of 39 respondents agreed) [11].
3. It is feasible for hospitals to comply with all guidelines for medical specialists (15 of 39 respondents agreed) [11].

Setting

Three hospitals were selected, from each of which three people were interviewed by one of the authors (LHKB); specifically, these were a member of the board of directors, a member of the executive medical staff, and the manager of the quality and safety department. These interviews were performed between November 2015 and January

2016, using a semi-structured approach. As compliance management is broader than the application of guidelines, the interviews also touched upon broader issues and other external demands that hospitals have to adhere to. The external demands also include guidelines from allied healthcare associations and non-clinical regulations “such as standards, guidance, indicators, laws, rules, regulations, (volume and quality) norms from insurance companies, letters and reports from the inspectorate” [16,17].

Interviews and data analysis

Formal face-to-face interviews were conducted individually with the participants in the respective hospitals. The researchers developed and used an interview guide in the form of topics and example questions to be addressed during the interview. Topics that were discussed in the interview included: governance of guidelines in hospitals, recommendations, and the need for guidelines. The interview guide was developed by LHKB and tested by DD, NVW, JB, and AS. After the first interview, the researchers evaluated the processes positively. The interviews were audio-recorded and transcribed verbatim for analysis [18]. The interviews were estimated to take 45 minutes. Field notes were made during the interviews, which lasted 26 to 48 minutes. All identifying text was removed. The results were returned to the participants for comments after the analysis took place. The interviews were entered in Atlas.Ti and coded (LHKB).

For the coding procedure, deductive and inductive content analysis was used. First, we coded deductively, using codes we retrieved based on the research question and the theory of the evidence pipeline. In a second round of coding we used inductive (open) coding to find additional insights that were not covered by theory. Examples of the inductive codes are ‘refused application’, ‘own vision’, and ‘act according to’. Afterwards, axial coding took place, where codes were ordered and checked [19]. Hereafter, all codes were structured into categories. Six themes emerged from the results. All but one of the themes described how hospitals prevent leaks. One theme describes the difficulties surrounding guideline adherence and, therefore, possible leaks. The themes are displayed using a thick description with selected key quotes. A summary of the themes is presented

in tabular form at the end of this article, reflecting the actions taken by each hospital for each pipeline step.

Ethics approval and Informed consent

The study was approved by the ethics committee (METC); 15N187. The study was registered in the Dutch Trial Register. At the beginning of each interview, participants gave informed consent.

Results

First, the results of the survey are briefly described. Then, the results of the interview analysis are described in detail using six themes. In the discussion, the findings of the interviews are compared with those of the survey.

1. Survey findings

Unlike the responses from the positive deviant hospitals that we selected for the interviews, many survey respondents reported problems in ensuring compliance with guidelines and problems with the division of responsibilities for guideline adherence in their hospital [11]. In Table 5.1, previously unpublished attitudes and opinions of survey respondents are presented.

From Table 5.1, it is obvious that supervisory activities of the regulator influence how hospitals establish priorities in their hospital: 92% of respondents agree that priorities of the Inspectorate influence the priorities of a hospital board. However, there is a certain ambiguity in the opinions expressed by the respondents; on the one hand, 75% agree that enforcement by the Inspectorate is important to ensure that hospitals provide good quality of care, but on the other hand, according to 81% of the respondents, the topics which are enforced by the Inspectorate are not always the topics that are most important for the quality and safety of care in their hospitals. Enforcement is regarded as top-down control by 78% of the respondents, whereas all respondents agree that they should be able to deviate from guidelines if they have good arguments for doing so. As reported in Blume et al. [11], 97% of the respondents stated that it is important that hospitals adhere

to guidelines for medical specialists. Respondents agree that hospitals should be able to dismiss medical specialists who do not comply (Table 5.1).

Table 5.1 – Percentage of respondents (n=39) that agree or completely agree with the following statements

To what extent do you agree with the following statements?	Agree %
Hospitals should be able to deviate from guidelines for medical specialists, assumed that they provide a good argumentation	100%
Hospitals should be able to dismiss medical specialists who do not comply with guidelines that are applicable to them or to be able to disconnect the admission agreement (as a last resort)	97%
It is important that our hospital has an overview of guidelines for medical specialists	95%
It is important that our hospital has a process that ensures that medical specialists are familiar with the guidelines for their scope of application	95%
Priorities of the Inspectorate influence the priorities of a hospital	92%
The topics which are enforced by the Inspectorate are not always the topics that are most important for quality and safety for the care in our hospital	81%
Enforcement by the Inspectorate leads to top-down control on compliance with guidelines for medical specialists.	78%
Enforcement by the Inspectorate is important to ensure that hospitals provide good quality of care	75%
It is clear which guidelines for medical specialists are enforced by the Inspectorate	33%

Table 5.1 also shows that respondents feel the need to have an overview of guidelines and a need for a process that ensures that medical specialists are familiar with the guidelines and their scope of application. In the interviews with the positive deviant hospitals, we sought out good examples of putting such a process of compliance management in place.

2. Interview findings

Six themes emerged from the interviews: cooperation, size, commitment, utility of guidelines, intrinsic motivation, and barriers to guideline adherence. These themes will be

explored below. An overview of how hospitals close leaks in order to organise adherence to guidelines is presented in Table 5.2.

Table 5.2 – How do hospitals organise adherence according to the pipeline?

	General hospital	Specialist centre	Tertiary teaching hospital
Are aware of guidelines	- Awareness of guidelines' content and trends of guidelines present at both central and department levels	- No awareness at the central level, but present at the department level	- Awareness of guidelines and trends present at central and department levels
Accept guidelines	- Guidelines are accepted. Intrinsically motivated, as they want to meet the demands (comply or explain) - Board and medical staff discuss issues together	- Guidelines are accepted. Compliance is considered mandatory - They want to understand the purpose of the guideline	- Guidelines are accepted. They strive to comply, but they screen them with a critical attitude as there are too many guidelines to adhere to - They do not have a central overview, as the overview of existing guidelines is expected at department level
Find guidelines applicable	- In general, participants find guidelines applicable - If not, then they enter into dialogue with the regulator	- Yes, but they remain pragmatic and critical if necessary - Applicability is checked at the department level	- Emphasis is on incorporating guidelines within existing processes and generating protocols. They do not expect that every employee is aware of guidelines, as long as they adhere to protocols

- Table 5.2 continued -

	General hospital	Specialist centre	Tertiary teaching hospital
Are able to implement guidelines	- If there are problems with applicability, then internal consultation with the board of directors takes place and eventual referral to the regulator	- Too many guidelines to comply with, hence pragmatic approach to implementation	- Guidelines have a major financial impact and therefore limit implementation of all guidelines - Inability to comply with the protocol/guideline have to be reported immediately and not at the moment that compliance is investigated
Act on guidelines	- They adhere to the guidelines. They ensure that there is allowance to deviate from guidelines (with justification) - Responsibilities are established at department level	- In general, they adhere to guidelines - The medical specialists are responsible for adherence to the guidelines	- In general, they comply with guidelines. Feel that the only way to monitor compliance is through internal audits

Cooperation

The interviewees emphasised that cooperation between the board of directors and the medical staff is essential to be able to implement guidelines at the point of care delivery (Table 5.2). Together, the board of directors and the medical staff are aware of the guidelines and discuss the expectations which are placed on their hospital. Then, in the face of resource constraints, they deliberate which guidelines should receive priority:

In our hospital, it is true that the board of directors and the executive medical staff work together closely, especially when it comes to substantive subjects. You are trying to prioritise instead of distributing the efforts equally. (Member of executive medical staff, tertiary teaching hospital)

In two hospitals, the board of directors and the executive medical staff set priorities together, which shows that they are interested in and take the time needed to assess guidelines. After a guideline is prioritised and accepted, they check its applicability and investigate what the implementation requirements are (Table 5.2). This increases involvement as they are investing in it with mutual effort:

You cannot always arrange everything for one another. You want to organise involvement. (Member of board of directors, general hospital)

Members of medical staff and management indicated that they undertake large implementation projects together.

If it is something with a big impact (...) it will be discussed between the executive medical staff and the organisation, of course. We consult each other regularly, the staff and the board of directors. What do they need from us, what do we need from them? What should be done, who is responsible? These things are discussed and then a plan of action is set up. (Member of executive medical staff, general hospital)

In conclusion, several participants highlighted that cooperation between the medical staff and the hospital management is important for the implementation of guidelines.

Size

During the interviews, participants referred regularly to the size of the hospital in relation to compliance. The hospitals (1000–4200 employees) classified themselves as being small compared with other hospitals in the Netherlands. Participants emphasised that they experience little or no distance between the board of directors and the staff due to the small size, with the result that they do not get embroiled in bureaucracy. The board of

directors was described as approachable. Awareness of guidelines, distribution, and implementation are arranged practically, with as few bureaucratic steps and as little inefficiency as possible:

It helps, perhaps, that our organisation is not so big (...). Yes, I think the bigger you are, the harder it gets. Here you can still talk pretty easily to the financial administration and hear how they arrange things. Yeah, the lines are short and we are not easily bogged down in our own bureaucracy. That does help, I think. (Member of board of directors, specialist centre)

Participants have the impression that a small hospital size is favourable, as staff members are more likely to know each other compared with large hospitals.

Commitment

Commitment of the board of directors and the executive medical staff was a recurrent theme in the interviews. The participants felt that the board of directors and the executive medical staff have connections with the guidelines that are imposed on their hospital. They reported that they attempt to know the requirements and are attentive to the announcements of new guidelines.

We focus constantly on the outside world – what are the trends, what is the essence, where are we going, what will come toward us? (Manager of the quality and safety department, tertiary teaching hospital)

The data showed that participants proactively take guidelines that ‘enter’ their hospitals and make them their own. They create a connection between external expectations and their own organisation.

That is the art. What do we want? And you need to create a 'we' feeling. You should avoid it becoming an ownership discussion – 'they want us to do it' – that is what you need to prevent. It has to be 'we want to do it'. (Member of executive medical staff, general hospital)

Participants create ownership of the guidelines by considering how they fit in their own hospital organisation and structure. Upon detection of new guidelines, they integrate them into their own policy, through cooperation between the board of directors and executive medical staff, among other ways.

We approach it proactively. We push a little – what will be published? We recommend certain preparations to the board of directors (...). At that time, the board will also tell the management, this is a recommendation we have to adhere to. (Manager of the quality and safety department, specialist centre)

The participants feel that their process of handling guidelines is, to a certain degree, linked to external expectations, but they have enough room to make their own choices. Overall, the participating hospitals show commitment and feel ownership.

Utility of Guidelines

The word 'pragmatic' was mentioned several times by several participants regarding the manner of guideline implementation. Participants reported that they handle guidelines pragmatically and tend to look at the relationship between guidelines and internal policies and create a link. They do so by using the supportive parts of the guideline to improve their flows and disregard the parts disturbing their processes.

Use the people on the ground during the pragmatic thinking process. I can come up with it here from behind my desk. However, people on the ground roll their eyes if I turn up with these ideas and that does

not make sense. Instead, I can tell them that we have to adhere to the guideline and what the underlying goal is. How does this work for you and how can we improve it? Then they come up with wonderful ideas! Even the people working in the kitchen, the less educated, come up with wonderful ideas. That is how it works. The beauty is, they will adhere to it. They support it. (Manager of the quality and safety department, specialist centre)

By handling guidelines pragmatically, participants can deviate from the guidelines during implementation. The specialist centre indicated that they strive to focus on the purpose of the demand, which means that they do not necessarily implement it in the way that it is prescribed. They do so consciously and justify their actions:

Yes, we wholeheartedly comply with the demands, no matter whether we talk about substantive demands, policies, or funding demands. We comply with all of these. But we are becoming increasingly bolder and freer to sometimes say, this rule – as it is stated right now – we are not going to arrange it that way. In the meantime, we justify why we do it like that. We always keep the purpose in mind. (Manager of the quality and safety department, specialist care)

A number of participants reported that deviations are important and inescapable:

If we comply as a hospital with the guidelines of all specialty associations, and a few more, we will bankrupt ourselves. (Member of board of directors, tertiary teaching hospital)

In conclusion, if guidelines hinder or are not applicable to the hospital situation, participants search for the purpose behind the rule and ensure that the requirement is appropriately calibrated to the internal policies.

Intrinsic Motivation

Participants are highly motivated to work according to guidelines, as they believe that this contributes to a better quality of health services. According to Berdud, if someone is intrinsically motivated, one gains enjoyment from an activity and acts in a self-motivated way instead of feeling controlled [20]. Participants reported that they are intrinsically motivated to meet external expectations:

We are an organisation that feels that we must comply with all laws and regulations. If they are coming, then the organisation is ready to follow them up. (Member of board of directors, tertiary teaching hospital)

The participants strived to autonomously anchor guidelines. They integrated guidelines in their own vision and involved employees during implementation.

The Inspectorate is often a reason to change. But we try to integrate the change in our own vision, too. I am convinced that signals from the outside world can serve as a threat, but I'd rather act on the assumption of intrinsic motivation. Therefore, I try to connect to it. I think: 'if this is the external shift, how can we ensure that it strengthens the internal organisation?' And that is the link. (Manager of the quality and safety department, general hospital)

Participants from the general hospital investigate how national movements can strengthen the activities within their own hospital and if possible, contribute their expert knowledge during guideline development before publication at the national level. This allows them to maintain their own culture and continue to follow external movements simultaneously. They have achieved intrinsic motivation by involving all employees and professionals in the organisation during guideline implementation from the beginning and

by ensuring everyone understands the importance of introducing something new or different.

Barriers to guideline adherence

Interviewees pointed out that implementing guidelines is not always feasible in practice. Participants repeatedly stated in different ways that there are too many guidelines, that they are too ideal, and that there are not enough resources (money, staff, facilities) to implement them in practice. This necessitates guideline prioritisation. It was reported that it is possible that physicians do not sense this responsibility.

The specialty associations have very little feeling for practical feasibility (...). The bad thing is, we are all members of a specialty association, and we are all responsible for the fact that guidelines are detached from the work floor. (Member of executive medical staff, tertiary teaching hospital)

There is room for improvement concerning their actions if something changes nationwide.

The treatment frameworks are adopted nationwide. You would actually expect that as soon as a treatment framework is updated, we would look closely into it and ask: do we still meet the criteria? I think there is room for improvement for the medical staff and also for the organisation to look more precisely into the variance. (Member of executive medical staff, specialist centre)

Participants stated that the production and coordination of guidelines are unstructured and difficult to follow. Guidelines are distributed over many different expert groups; therefore, hospitals should actively arrange them, instead of relying on structured dissemination. The production and publication of guidelines is not foreseeable and limits awareness. Numerous participants indicated that when looking at guidelines in isolation

from each other, they have added value. However, it is not feasible to look at the total amount. As a result, a patient may be the victim of several guidelines and regulations:

Imagine that we have children [patients at the specialist centre] who have to be paid for by four different funding sources, to simply pay for the regular care for a child. Those are four different guidelines! (Manager of the quality and safety department, specialist centre)

Participants stated that staff and physicians must make special efforts to generate protocols which are based on different guidelines to be able to act accordingly. Summing up, differences between the theory and practice are experienced in hospitals. Even though hospital staff are motivated to create a link between policy and implementation, they need to prioritise.

Discussion

In this study, we explored how hospitals ensure that guidelines are used in practice. During the interviews, themes were identified which were used by the participants to organise the pipeline and prevent ‘leakage’. Table 5.2 describes how hospitals organise adherence more practically. We will first describe the themes and compare them with the survey findings.

There is some evidence that implementation is less likely if there is a lack of motivation, priority, and awareness [21]. The interviews show that **commitment** and **intrinsic motivation** by the medical staff, the board of directors, and the manager of the quality and safety department are key factors to make sure that guidelines are generally known, considered, accepted, understood, and implemented (i.e., by physicians, nurses, managers, and all other hospital staff). Hospital strategies and structures that support commitment and intrinsic motivation are therefore likely to give an advantage in the effective implementation of guidelines. Furthermore, these strategies might be a pre-condition to making guideline implementation a collaborative effort. Additionally, we have found the adaptation of guidelines to be an effective strategy. This board strategy leaves

room to deviate based on practical considerations that might be locally determined. Guidelines are created externally and it can be challenging to be aware of all of them. A hospital is less likely to implement a guideline if resources, time, or understanding are lacking, which shows that guidelines are not applicable in every situation. It is essential to understand the **utility of the guidelines** and handle them pragmatically, which means that understanding and implementing the purpose of the guideline is more important than the mode of implementation. Hospitals actively try to create a link between the policy and implementation of guidelines: if the intervention is incorporated into existing processes and activities, implementation is more successful, which has also been found to be the case elsewhere [22].

We have found **cooperation** – especially between hospital management and medical staff – to be an advantageous factor of an effective implementation strategy, enabling the introduction of guidelines at the point of care delivery. If one is aware of guidelines, cooperation can lead to endorsement, which could prevent a leakage between awareness and acceptance. We recommend boards of directors and medical staff exercise cooperation and joint responsibility within hospitals in order to master the complexity of moving from awareness to adherence. After that, responsibilities for implementation need to be spread and adopted.

Another success factor enabling the introduction of guidelines at the point of care delivery appears to be hospital **size**. Studies have produced contradictory evidence that bigger is better, but also that smaller is better [23,24]. However, the participants in this study underlined that the smaller size of their hospitals helped to prevent leakage, as a short distance between the common players helps to prepare for implementation [25].

Interestingly, even though the hospitals were intrinsically motivated and tried to implement guidelines, all of the participants declared that adherence to guidelines was challenging as there were differences between theory and practice, which interfered with the implementation of guidelines. The sixth theme of the interviews – **barriers to guideline adherence** – showed that hospitals are, despite all their efforts, struggling to adhere to guidelines. Hospital staff stated that they are overwhelmed by guidelines as there is a labyrinth of requirements. If a hospital is overwhelmed by requirements, they

are less likely to actively search for different trends and new publications. They are more likely to wait until someone else sets priorities for them. After external prioritisation and enforcement is completed, they work on implementation. If we simply look at the pipeline, awareness seems to be the weak spot – if a hospital does not know that a guideline exists, they cannot decide to apply it or not, as they are not aware of it. This is in line with the results from the survey. In contrast with the first five themes, the survey and the sixth theme (**barriers to guideline adherence**) shows that hospitals are more influenced by the regulator and link guideline implementation to internal and external audits. Boards and professionals cooperate less effectively than the participants from the interviews; however, they stated that dual responsibility would be desirable.

The design and development of guidelines take place outside of hospitals. Simultaneously, professionals can influence the development of guidelines, as they are members of specialty associations. However, most professionals do not exercise their right to influence guideline production to make them more feasible. At the same time, physicians possibly do not sense their responsibility to guideline development and the implementation of new guidelines and regulations [26]. This might be because there is an abundance of guidelines developed by multiple actors without central coordination [27]. It takes a lot of effort to stay up to date and one can assume that the vast number of guidelines might be the cause of issues regarding the insufficient awareness of hospitals and physicians. This might lead to the normalisation of deviance in healthcare delivery [28]. Choices are made without a fair balance of the available guidelines. Further research is needed to discover how these choices or even priority settings can be supported.

This study has some limitations which should be highlighted. The results from the interviews are based on the perceptions of the respondents. We did not study whether these actually lead to better compliance or not and how guidelines are used on in the workplace. A further limitation is that we only studied the central level of the hospital; specifically, the board, management, and executive medical staff. Another possible limitation is that this topic is sensitive and is, therefore, susceptible to socially desirable responses. Interestingly, some people felt freer after the recording device was turned off

and added extra elements to the interview. Notes were taken and the content was added to the recorded material, hence reducing possible bias in this respect.

Conclusion

The hospitals in our study find guidelines necessary and useful. They take responsibility and create a link between policy and the implementation of guidelines. Hospitals have the power to minimise leakage if boards of directors and medical staff are committed, intrinsically motivated, cooperative, and use the guidelines pragmatically. If resources are scarce, priorities among guidelines need to be established. Comparing the results from the interviews and the survey, it can be concluded that hospitals experiencing problems (survey) focus more on the external expectations, creating defensive behaviour; while hospitals experiencing fewer implementation problems (interviews) focus more on integrating guidelines into their own policies.

What is needed in the future? The accessibility of guidelines must increase so that, consequentially, awareness can increase. Moreover, fewer guidelines with less complexity are needed, while at the same time deviance should be accepted in the sense that guidelines are never definitive and there will not be a moment where all compliance is regulated. Hospitals need to set up a process where they define the next steps after the publication of a guideline. The key messages for guideline users and guideline developers can be found in Box 5.1.

Do's – guideline users	Do's – guideline developers
<ul style="list-style-type: none"> • Facilitate cooperation between hospital management and clinicians • Keep the distance short between management and the work floor • Be committed to the purpose of guidelines • Be aware of the production and organise the distribution of guidelines • Find and use intrinsically motivated staff to enhance the implementation of guidelines • Influence guideline development through participation and co-creation • Set stepwise priorities if you cannot implement all guidelines at once 	<ul style="list-style-type: none"> • Harmonise and standardise production and distribution of guidelines • During development and updates of your guidelines, keep in mind that other parties also impose guidelines on guidelines users • Bear in mind that developed guidelines can also be used for enforcement purposes • Be clear about the allocation of responsibilities for the guideline recommendations – who is responsible for what? • Be explicit about the level of obligation: is it obligatory/optional/advisory?

Box 5.1 - Key messages for guideline users and guideline developers

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Chapter 6

The inherent perils of (the multitude of) guidelines – a focus group study of stakeholders' perceptions

Under Review

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Abstract

Background

Hospital boards have the responsibility to ensure compliance of hospital staff with guidelines and other norms, but they have struggled to do so. The aim of the current study is to identify possible solutions that address the whole chain of guideline and norm production, use and enforcement and that could help hospital boards and management cope with norms and guidelines.

Methods

We performed a qualitative study of three focus groups involving a total of 28 participants. In the third focus group, no new themes emerged, indicating that saturation was achieved. Focus group discussions were audiotaped and transcribed verbatim. Results were coded, and three themes emerged from the results. Thick description with selected key quotes is used to display the themes in the result section.

Results

In the first instance, norm developers, norm enforcers and norm users acknowledged and reformulated the problem before they suggested solutions – the proposed concrete solutions, such as clear description of the division of tasks within guidelines, clarity about the purpose of guideline recommendations, a maximum number of quality indicators for hospitals and implementation of an ensuring proper Information Technology (IT) infrastructure.

Conclusions

This research showed that guideline implementation is not just a hospital problem. All stakeholders should combine their efforts to optimise the chain of guideline production, use and enforcement. This should be addressed at the healthcare system level.

Background

The use of guidelines and norms is supposed to provide clinical practice with the scientific basis that is required to justify the pursuit of consistent and safer health care delivery [1]. Even though evidence-based medicine (EBM) is the golden standard for decision making and has its obvious advantages [2, 3], an increasing number of disadvantages are also being observed [4]. Potential guideline users feel uncomfortable, over-controlled and angry due to regulators and inspections [5]. Apart from that, EBM has reached a point where the sheer volume of guidelines is a problem itself [6-8]. A conceivable strategy to address this problem will therefore be to reduce the disadvantages of implementing the guideline without losing the benefits. This is particularly problematic in hospitals, where all kinds of patients with innumerable (combinations of) diseases are treated, as a result of which employees and professionals from a variety of disciplines have to be familiar with guidance produced by many organisations [6].

Guidelines are part of the external demands with which hospital boards, management and staff have to comply. But there are also other norms to which a hospital should adhere in the Netherlands [7, 12], for example, obligations to publish quality indicator scores, consensus documents or laws and regulations. External demands include guidelines from non-clinical regulations and allied healthcare associations “such as standards, guidance, indicators, laws, rules, regulations, (volume and quality) norms from insurance companies, letters and reports from the inspectorate” [7, 12, 13]. In earlier studies, we focused on the strategies that hospital boards and managers adopt to cope with these demands. However, when it comes to compliance with guidelines and norms, there is only so much that hospital boards, managers and staff can do (further referred to as hospitals). Some issues are beyond their sphere of influence. Therefore, in this study, we aim to look for solutions that address the whole chain of guideline and norm production, use and enforcement. The system is larger than a hospital itself, and actors/stakeholders around it have a lot of influence on the daily challenges a hospital faces. To increase the quality of care, it is essential that stakeholders involved in guideline development, implementation and monitoring work together [4].

The question we therefore asked ourselves was: How can institutions that produce norms and guidelines for hospital care (e.g., patient organisations or professional associations of clinicians and nurses, guideline developers, trade unions and policymakers) and institutions that enforce these norms (e.g., the inspectorate for health care and insurance companies) contribute to improve the capacity of hospital boards, managers and staff to improve care with guidelines?

This article focuses, on the one hand, on the interaction between these stakeholders and hospital boards. On the other hand, it focuses on norms and guideline processes: the whole chain of conception, dissemination, implementation and enforcement. More specifically, we looked at:

- what developers of norms and guidelines for hospital care can do to reduce the amount of guidelines/norms and improve the clarity and consistency;
- what norm-enforcing institutions can do to focus and align priorities and reduce uncertainties for hospitals for which they are expected to comply;
- what hospital boards, managers and staff can do to successfully integrate norms and guidelines into hospital systems.

The aim of this study is to identify possible solutions that help hospitals to cope with norms and guidelines within hospitals, focusing on the external context. The findings might be useful for hospitals to handle norms and help policymakers to design better systems.

Methods

We chose a qualitative research methodology for this study and closely followed the Standards for Reporting Qualitative Research (SRQR) criteria to preserve the quality of this study [10]. We conducted three focus group interviews in the Netherlands to gather the information we needed to answer our research questions. Our rationale for choosing this method was to collect a lot of data from experts within a short period of time [11]. Furthermore, if the prior knowledge about a topic was sparse, the group dynamic could help extract rich data, as participants can actively think about existing processes and express new ideas.

Participants

Focus group participants from various parties in the healthcare sector were recruited in three different ways: (1) the authors invited participants of umbrella organisations, patient organisations, guideline development organisations, hospital board members, quality and safety managers and employees from hospitals, doctors, inspectorate and patient federation by e-mail; (2) invitations were placed on three online forums where possible participants are active (tertiary teaching hospital, trade association for general hospitals, software vendors for Dutch hospitals); (3) invited participants were asked to distribute the invitation to other possible relevant participants. Eligible participants had to work in the Netherlands in the health care sector, speak Dutch and had to be impacted by guidelines in their day-to-day work. The number of participants and the no-shows are described in Table 6.1 (N=28).

Table 6.1 – Participants of the focus groups

Focus group	Number of participants and no-shows	Norm developers	Norm enforcers	Norm users	Researcher/consultant/policymaker
1	10 participants (12 applications, 2 unsubscriptions)	3	2	1	4
2	12 participants (12 applications)	4	1	7	0
3	6 participants (10 applications 2 unsubscriptions 2 no-shows)	2	1	2	1

In total, three focus groups were conducted in Utrecht in August and September 2016. After the first focus group, the moderator and researcher evaluated the process and decided that it was not necessary to adjust the structure. The second focus group generated the most relevant information. In the third focus group, no new themes

emerged, indicating that saturation was achieved and refrained from conducting additional focus groups.

Procedure

The participants received the invitation with three published articles [7, 12, 14] from the authors about hospitals and guideline implementation to create a common starting point for the discussion. They were asked to think about three questions (Table 6.2).

Table 6.2 - Focus group semi-structured topics

Function/focus	Key questions
Questions on invitation	<ul style="list-style-type: none"> • What can developers of norms and guidelines for hospital care do to reduce the amount of guidelines/norms and improve clarity and consistency? • What can norm-enforcing institutions do to focus and align priorities and reduce uncertainty for hospitals about what they are expected to comply with? • What can hospital boards, managers and staff do to successfully integrate norms into hospital systems?
Hospital as part of the system	<ul style="list-style-type: none"> • What are possible solutions on system level?
Norm developers	<ul style="list-style-type: none"> • What solutions can guideline developers put forward?
Norm enforcers	<ul style="list-style-type: none"> • What can norm enforcers contribute to a possible solution?
Stakeholders view	<ul style="list-style-type: none"> • Input from parties outside the hospital concerning experience problem by hospitals
Different perspective	<ul style="list-style-type: none"> • Possible solutions from a different perspective?

At the beginning of each session, the moderator (DD) explained the purpose, and procedures. This was done to ascertain that all participants had a similar level of knowledge about the topic, from where the discussion can start. The researcher (LB) was present during the focus groups but did not contribute unless clarification was required. The researcher audiotaped the focus group discussions and took notes during the focus groups. The participants were stimulated to express their opinions freely, and it was

explained that all identifying text would be removed for publication. Only the moderator, researcher and participants were present during focus groups, and all participants signed an informed consent form. Each focus group lasted one and a half hours. A semi-structured interview guide was tested by the co-authors and used for moderating. The topics are shown in Table 6.2. It was determined beforehand that three or four groups could be conducted, but after three focus groups, data saturation was reached. The researcher transcribed the focus groups verbatim. Transcripts were not returned to the participants.

Three of the authors (JB, NvW, LB) independently read the transcripts thoroughly [1]. They coded the data openly and extracted key issues and underlying themes from the data. After that, the codes were ordered and checked [15]. Three themes emerged from the results, one theme having four sub-themes. All authors validated the themes. Thick description with selected key quotes is used to display the themes in the result section.

Results

In this section, the themes that emerged from the analysis of the focus group transcripts are presented. A total of three focus groups were conducted involving 28 participants.

Acknowledging perceived difficulties

During the introduction of the focus group, the moderator specifically explained that the problem of implementing guidelines in a hospital was described in previous research (of which all participants had received the publications) and stressed that the aim of the focus groups was to look for solutions. Nevertheless, the participants from all categories once again acknowledged during all focus groups that the problem exists. They confirmed that there exists a sense of urgency to find solutions in hospitals and with stakeholders.

What you or they [pointing to guideline developers] release into the world is not a lot, but all of them together create a jungle (Norm user 8).

Participants emphasised the burden that perspectives are neither harmonised nor aligned. On the one hand, developers perceived that they support practitioners by developing

guidelines and indicators, resulting in requirements owned by the sector. On the other hand, hospitals and professionals perceived those as a burden instead of support.

I, as professional, am assisted if I can find and access things easily, as soon as I have a question (Norm user 4).

We make the guidelines to assist professionals and patients, of course. If we disturb others with it, it is sad. We have to investigate together how we can find a good solution so that everyone is assisted (Norm developer 4).

Participants stated that hospitals want to provide good care, but norms can have an unintended (and maybe unwanted) impact. They felt that their resistance appeared from the plurality of musts/guidelines and the resulting impossibility of guideline implementation. All participants emphasised that the system of guidelines and norms did not assist professionals adequately and that it needed to be organised more effectively and efficiently. The Dutch Surgical Colorectal Audit makes information publicly available, leading to the following example of impaired effectiveness for quality improvement:

Anastomotic leakage in colorectal surgery is the indicator to assess whether you deliver good care or not. I am 100% sure that after we score poorly the first time, the surgeon does instruct the specialised nurse to look at it (the indicator and therefore, the registration) somewhat differently. Herewith, you completely miss your target. The indicator is used, in fact, to get a green checkmark. Based on this, health care is purchased! (Norm user 1).

Participants discussed that it is unclear which guidelines need to be followed and claimed that clear definitions are needed. Some referred to guidelines as quality improvement tools; however, others used them as enforcement tools.

We think that everyone must adhere properly to the rules and guidelines; the guidelines do not exist without a reason. But I can conceptualize that there is some need for more focus
(Norm enforcer 2).

All participants acknowledged the perceived difficulties presented in the previous research, accentuating what their point of view is. Further citations are displayed in Table 6.3.

Table 6.3 - Citations of participants reformulating the problem of guidelines

Citation	
‘People are not acquainted with it, they do not know it, they do not know what recommendations they have to know. It really depends on the interest of an individual professional whether it is used or not. I think that you need to look on system-level whether protocols are generally in line with guidelines. Quite often they are not even translated into practice. I think that it depends too much on the individual professional, and I think you should do much more on system level to implement it. And at the same time, I think, there is a problem with the system at organisational level.’	Norm developer 6
‘Yes, if you look at the register, for example. We are asked to provide a tripartite now, including insurers. Thus, it is agreed that insurers play an even more important role. That was not the original question for guideline developers, by definition. Not because one is against it, but one looked at the content and how to deliver the best quality of care.’	Norm developer 2
‘I think it is a very difficult discussion, because I also realize what hospitals encounter. All parties awaken me to that. On the other hand, it is also true, that we have chosen a system in the Netherlands, where patients have an understanding of the quality in order to make the right choices. And yes, you will need information to do so.’	Norm developer 3
‘I did notice that there was a certain reluctance to reformulate an indicator, because the insurers may call them on account, and that was sensed immediately.’	Norm developer 9
‘It is questionable whether the field is really waiting for guidelines the way they are presented now.’	Norm user 8

- Table 6.3 continued -

Citation	
'And then you have the perverse incentives on all sides, and the control of the board of directors is fundamentally absent. Absolutely absent. There is no testing, nothing. For me, DICA is an example how it should not be done.'	Norm user 2
'In the final phase, where you could start an improvement project, you cannot achieve it in practice, because you are hampered by so many factors. This is influenced by insurance companies, a patient, by available money or by management choices that must be made. So you have... What I am trying to say is that there is little room to establish improvement.'	Norm user 9
'As a matter of fact, I would like to say that hospitals do want to provide good care. The resistance comes from the multitude and impossibility.'	Norm user 1
'The challenge, therefore, is to provide the right information to the professional at the right time during the search. That is the big issue.'	Norm user 2
'But a guideline, if I may call it that way, is a tool. It is an invitation. We, as a group, have determined that this is the best approach, and we can deviate from guidelines if we argue well. An indicator, on the other hand, encourages reflection, which stimulates the consideration: what is good for one specific patient, but not for the other?'	Norm user 1
'When I think of a quality label, I see it as a reward. I also notice that it happens in hospitals. Professionals say: we should keep this quality label.' & 'In psychology, not getting a reward is a punishment.'	Norm developer 3 & Norm user 6
'... the whole exercise in the care sector was to deliver everything at one point in time for multiple purposes. But then you experience problems during realisation, as the insurers first said yes, but then they want to receive it at the first of October [<i>which is a different date than earlier agreed on</i>], because they need it for contracting. And then you have to work with the results from the previous year. So that is very difficult.'	Norm enforcer 1
'The minute that all enforcing institutions, the patient, the insurers, and inspection, look over your shoulder in the doctor's office, you might be more careful, perhaps you are going to make strategic choices instead of basing it purely on your professional expertise.'	Researcher/ consultant/ policymaker 5

Concrete solutions

Besides several reformulations of the problem, the participants named exact solutions. The solutions formulated by the participants can be categorised into four categories.

1. Be clear about the target (group) and the imposed obligation

Most norm users and norm developers agreed that norm- developing institutions should stipulate the tasks for the organisation and professionals precisely in their guidelines. One attempt was described:

We try to indicate in the guideline whether the registration relates to the organisation or the individual specialist, to achieve that the one in charge feels the responsibility for the registration.
(Norm developer 2).

After publication of a guideline, a hospital does not immediately undertake implementation action. They first decide which (part of the) guideline has priority. Participants suggested that certain criteria, such as risk reduction, quality benefits and health benefits, should be mentioned in the guideline to contribute to a decision.

Can't we do much more to highlight which things really make a big difference for the patient? (Norm developer 6).

Overall, participants underlined that distinction is needed between obligations and options as well as to whom they are relevant. One of the stakeholders from a norm-developing organisation put forward a suggestion that his organisation (and others) could follow.

Actually, you can say without difficulty: these are the guidelines having an organisational impact and we will create an executive summary, and we sent the executive summary to every board of

directors. That is only a small effort. We do not do it now, but it is one of the things we consider if that is what you are waiting for... You can also make a division into three categories: you can say this is purely professional, this is purely organisational, and this is something in between. Then you are already on the right track. And if you do want to link this with a timeline, you can also highlight what is most important (Norm developer 5).

According to participants, this would make the process of implementation and sharing of tasks during execution much easier for users.

2. Be clear about the purpose of a norm/guideline/indicator

In each focus group, participants reported that norm developers should distinguish between different goals and targets of guidelines and indicators and the goals of publishing.

We can still improve a lot. The separation of the aim/purpose (Norm developer 6).

Several participants stated that norm developers could indicate that some indicators are used primarily for patient choice and are not specifically intended to improve quality.

*Not all indicators are intended to improve quality (Norm developer 3).
No, some indicators specifically aim at patients who are still outside:
look, it is better here than there. This is a different purpose
(Additional norm developer 1).*

Participants stated that clear labelling of the purpose is desirable: which indicators are used to facilitate the choice for the future patients, which indicators are used for internal improvement, which indicators are used for contracts with insurers, etc. However, norm

developers cannot control how their produced norms would be use or whether the norms are used for other purposes.

Guidelines are used by the inspectorate to enforce or by insurance companies for purchase, while the main objective is still practice variation and knowledge transfer. However, the use by others is possible. Whether the use of the guideline turns out as intended or not, that is the question (Norm developer 1).

Measuring is important, as stated by several participants. One participant illustrated this with an example from 15 years ago, where the Netherlands and Belgium had different approaches for measuring MRSA:

Belgium had a long time no MRSA problem because they simply did not measure MRSA. Then you also 'have no problem'
(Norm enforcer 1).

Participants stated that norm developers should indicate within a guideline the value and necessity for the guideline. Otherwise, users might not recognise the impact.

The usefulness and necessity must be explained. And if people do not know why they are doing something. 'Yes, we need to do it for the board, or yes we need to do it for the inspectorate.' That does not work. They need to understand what is useful and necessary (Norm enforcer 1).

3. Work with a maximum frame for indicators

In the first focus group, particularly, a discussion took place about norms, with respect to public disclosure of quality indicator scores. Currently, Dutch hospitals are obliged to measure and publish about 1,500 quality indicators. Participants agreed that quality

indicators are useful but that a maximum number is required. Together, stakeholders should combine different indicators, according to the participants. After that, new ones can still be developed, but it can only be introduced after an old one gets erased.

Two years ago, we thought... Maybe we should use ONE indicator for multiple purposes. Then you limit the use of indicators and then you can use the same outcome for several things. (Norm developer 3).

Participants specified that if different indicators are combined, the indicators should then only be used for the purpose for which they were created. Otherwise, the media and other parties could hijack the data. Participants reported that some attempts at synergy were already being made.

Insurers compiled a top 30, which is slightly different than the national top 30 which was worked with (Norm enforcer 4).

As explained by one participant, the first efforts are being made in the Netherlands: On a national level, 30 conditions were selected to improve the available information for patients with all parties, involving, among others, understandable guidelines for patients and the registration and publication of information. At the same time, insurers agreed that they would establish a limited number of quality indicators for 30 conditions.

4. Ensure proper IT infrastructure

The participants explored different solutions within the IT area in all three focus groups to make guidelines more usable for health care.

You should be facilitated. We now have the new electronic health record, and even though it was promised before we purchased it, the registrations [referring to registration of quality indicators] are not

included. Well, I think that we need to take big steps to facilitate the professional in this (Norm user 7).

They proposed that norm developers could provide guidelines in such a way that all of them could be found at the same spot. Meta-information and summaries as well as implementation advisers should be included. Hospitals should join forces to find an IT solution to connect guidelines to work sequences, to achieve that guidelines can be easily accessed at the point needed. Therefore, electronic patient devices should be linked to guidelines.

I think that the whole support by IT to our professionals, is a challenge where we are in our infancy. And that these systems are simply not customised for our professionals yet. And I think that the people firing their systems at us, had too much to say so far, without us communicating clearly what we really need to make it work properly (Norm user 2).

The hospitals experienced dependence on the solutions electronic health record vendors provide. Participants proposed that hospitals should join forces to negotiate with the electronic health record vendors, as implementation requires a beneficial support at the particular time needed.

Well, the gap between IT in hospitals and the possibilities I have with this [points at his mobile phone], surprises me since years. (Norm user 4).

Participants suggested that norm-developing institutions could deliver guidelines and indicators in such a way that they are easy to integrate into the institutional IT support systems of users.

Improvement of system

The majority of solutions proposed by the participants take aim at the existing system. The concrete solutions, for example, focus on improvements in the existing system and do not suggest a different course. Additionally, they offer abstract ways to improve or name good examples from which one can learn. Participants referred to the system of the Dutch General practitioners as best practice, where all information needed is easily accessible via a website and an software application, without difficulties.

I think, that there is an international best practice of the Fins, again from the GPs, who did build the guidelines into their medical IT system. This initiative is from Finnish professional organisations. It is truly an example how they do it over there (Norm developer 6).

Participants stated that norm developers could increase transparency about how they publish and how they distribute guidelines.

We fool ourselves a little bit, as we are actually in a situation, I think, which is caused by us. By sharing too little what we do. I speak from a medical specialist perspective. Thus, you end up in a situation of disturbed mistrust (Norm developer 5).

Participants suggested involving managers and professionals: discover what they think is important and create more insight for them about the importance of implementation. After implementation, they proposed that managers and professionals should give feedback to norm developers about usability in practice.

And I think it is very sensitive to evaluate, as soon as it is fully developed and implemented, how it will be used in practice (Norm developer 8).

Participants recommended that the enthusiasm of doctors must be facilitated, to create bottom-up appetite/willingness and to address the relevance of the core of the guideline from the eye of the professional.

I would say that there needs to be willingness by the professionals to share information. You cannot enforce that externally. Make it a habit and necessity (Researcher/consultant/policymaker 5).

The solutions put forward by the participants aimed mainly at a change in culture, where it remained unclear who is responsible for what and when. They suggested finding alternative ways for hospital boards and managers to be in control. Additionally, they suggested strengthening the professionals.

You have to create much more freedom in your system, to be able to work with local guidelines that are not enforced, but which are used to deliver the best care for the total patient population. That is the freedom that you need (Norm user 1).

What I do believe is in strengthening the professional, both the physician and the nurse (Norm user 1).

Discussion

In this study, we looked for different possible solutions to help hospital boards, managers and staff to cope with norms and guidelines. While this focus group study specifically aimed for solutions, participants were not tired of repeating that norms and guidelines, including quality indicators, became unfathomable and unmanageable [6, 14]. Norm users, norm developers, norm enforcers and researchers/consultants/policymakers acknowledged the struggle of hospital boards and managers, described in previous research [6, 12, 14] by giving various examples and different interpretations of the

problem. Norm users experience guidelines as a burden instead of support, as the guidelines are often not available in a form that can be acted upon at the time decisions must be made [16].

Most suggested solutions were made within the current system. The results show that guidelines should state the target group of a recommendation and whether the implementation of this recommendation is obligatory or voluntarily. As norm enforcers are nowadays more likely to use guidelines during enforcement activities, there is a fine line between the 'best practice' and 'standard of care', as described by an American study [17]. Our study shows that there is a need to set priorities, to be able to choose which (parts of) the many guidelines should be implemented first. Herewith, a helpful point of reference can be created for those responsible for priority setting in implementation, and to guide enforcement agents using guidelines as a basis for enforcement activities.

Different stakeholders value different aspects of quality of care, and therefore, many indicators are developed [18]. Indicators that are used to monitor the quality of hospital care are resource intensive, and one perceived barrier of using indicators is the lack of resources [19]. Our results show that the participants perceive that many indicators do not label the desired purpose, and that participants wish for a maximum frame for indicators.

Our results show that the purpose of a norm/guideline/indicator needs to be clear. This is in line with the framework of guideline implementability, emphasising that a stated purpose of the guideline (e.g., clinical decision making, education, policy, quality improvement) may improve the actual use of the guideline [20, 21]. The motivation to comply is higher if the benefits of the guideline are highlighted [22]. Further research is necessary to understand if a clear purpose increases the actual use of the guideline. Additionally, we need to fasten up the transformation to a new IT-directed guideline support system. The literature shows that the health care world is already busy with the enhanced use of computerised clinical guidelines [23]. Trivedi already highlighted barriers and solutions back in 2002 [24], whereas our research shows that Computerised Clinical Guidelines have not yet been largely implemented in the Netherlands (besides at the General Practitioners). Research in other countries, such as Italy, shows that this leads to

process-of-care improvements [25]. Since the transformation also costs money, there is a need for a business case.

Throughout the focus groups, it became clear that forces must be bundled to reduce obstacles to the use of guidelines. Regular consultations in an appropriate form between the parties could enhance the overall chain, and a feedback mechanism between the three parties could help to improve coherence. Further research on the coherent improvements would be interesting.

Interestingly, the suggested solutions were all directed at the current system and the chain of guideline production instead of a whole new course for guidelines use. The question was raised about whether guidelines are used for what they were intended, but it was not entirely questioned whether it is an appropriate tool for health policy in general [26].

Study strengths and weaknesses

We recruited stakeholders with various backgrounds and occupations. The moderator ensured contribution by all participants by starting with an introduction round to accustom all participants to talking in the group and finished with a round where participants could contribute their closing thoughts. A possible limitation is that the participants received three published articles with the invitation which might have influenced the discussion. Furthermore, some participants knew each other, since they are experts in the healthcare sector in the Netherlands. However, at the same time, it is a strength that the different parties discussed common objectives and possible improvements, as it had not happened elsewhere in this composition until these focus groups. Further research on possible solutions for guideline usage could provide clues for system changes to achieve improved quality of care.

The study was conducted in the Netherlands, which has a privately operated system based on regulated competition and with decentralised guideline development, but with centralised indicator development. Therefore, the generalisability might be restricted. However, as other countries also struggle with proliferated guidelines and seek answers

for: ‘Why are there so many guidelines? Are they all important, and how did we get here?’ [17].

Conclusions

This research showed that hospitals must join forces to become active players in the process of guideline development, so that four concrete solutions described in the result section can be addressed collectively at the national level. Together, stakeholders should combine their efforts to optimise the chain of guideline production, use and enforcement at the healthcare system level. Participant’s believe that implementation is not only the responsibility of hospital boards and professionals and suggest that the responsibility distribution for guideline implementation should be adjusted. If hospitals do not become an active player at national level, we will continue to muddle through it, and that would be a waste of everyone’s effort.

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Chapter 7

Good intentions getting out of hand – is there a future for health care guidelines?

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Abstract

To date, the focus of research on guidelines has been directed toward professionals, and hospitals have merely served as the context. Little research has been performed on the dilemmas of guideline adherence in hospitals, as a setting in which multiple professional guidelines have to be implemented simultaneously; also, it is still unclear which clinical guidelines have to be aligned with other external demands, such as rules, regulations, standards, indicators, norms, and so on. Hence, different ways of studying the issue of guideline implementation are called for.

Introduction

In the 1990s, guidelines were introduced in health care delivery as a tool that could bring state-of-the-art scientific evidence to professionals who were no longer able to keep up with the ever-growing amount of applicable evidence in the scientific literature. Clinical practice guidelines were defined as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”¹ The recommendations in the guidelines were expected to improve the decision-making process between clinicians and patients,² thereby making the task of evidence-based decision making much easier. Evidence-based medicine had its successes, as it has improved the quality of care received by patients.²

However, in recent years, researchers have become increasingly interested in the failure of guideline implementation. For example, Banja³ found that deviant practices in health care were standard. Evidence-based medicine was also described as a movement in crisis.⁴ Systematic reviews, research, and opinion papers in the literature that attempted to explain the reasons behind the non-compliance of guidelines revealed some explanations for this.^{5–10} These included implementation issues related to the characteristics of 1) the guideline themselves (eg, reliability, trustworthiness, validity¹¹); 2) those who apply them (eg, professionals, nurses, chemists, etc.); 3) the patients they concern (eg, problems with adherence in case of multimorbidity); and 4) the context in which they are being applied (eg, hospitals, other institutions). To date, the focus of research on guideline implementation has been on the first three characteristics and less about the last characteristic, that is, context.¹⁰ This lopsided focus on the research has turned out to be a problem as the application of most guidelines occurs within the context of an institution.

Furthermore, professionals have mostly been the unit of analysis for implementation studies and the institutions – when considered – have merely been the context. Little research has been performed on the dilemmas of guideline adherence in hospitals, as a setting in which multiple professional guidelines must be implemented simultaneously, and in which clinical guidelines have to be aligned with other external demands, such as rules, regulations, standards, indicators, norms, and so on. Guidelines and evidence from

scientific research are used and combined with policy, and enforcement organizations base their decisions on guidelines.^{12,13} In contrast to the supportive function guidelines are intended for, they are also used as enforcement tools in the Netherlands.¹⁴ Furthermore, the target groups subject to this enforcement process have been expanded to include hospital board of directors, as they are explicitly responsible for monitoring the adherence to guidelines.¹⁵ It is given that in many local and national health care organizations, several guidelines exist that have been found to be changing at a very fast pace, thereby creating increased uncertainties as to what to adhere to in clinical practice.¹⁶ Therefore, it was assumed that focused exploration of these dilemmas could reveal previously unnoticed challenges within the health care delivery process.

Guideline development, guideline adherence or behaviour change by professionals was not investigated, as this has already been the focus of various studies in the literature;¹⁷ instead, the authors decided to conduct a series of studies to identify the problems with the implementation of guidelines from the hospitals' perspective.^{18,19} Some dilemmas emerged during this process, which are discussed in this perspective paper.

Dilemma 1 - Centralized versus decentralized development

If scientific evidence is to be used in practice, the adoption of guidelines in hospitals is essential. To achieve this, guidelines need to be disseminated structurally, so that hospitals are aware of them. It was emphasized that hospitals need to be aware, as the board is in charge of the compliance management. A hospital cannot comply with a guideline that the hospital management or professional staff does not know.¹⁸ Moreover, members of the organization should be able to accept the guidelines as trustworthy and helpful. In countries like the United States, Belgium, and the Netherlands, guidelines are developed, prepared, and disseminated by various developers and professionals and not by a centralized body, such as a central government agency.⁸

This decentralized development and dissemination, in which professional groups are in the lead, increases the chances of support and awareness by professionals for the guidelines that were developed and authorized by peers. While the efficient dissemination of guidelines can enhance adherence to recommendations, developers of guidelines in

many countries have failed to agree on the standardized, streamlined development of guidelines as well as in the process of their authorization and dissemination.²⁰ If structured development and dissemination are missing, it becomes difficult for hospitals to know which guidelines to adhere to, leaving many hospital boards with a “lack of control.”²¹ In other words, decentralized development may increase acceptance but hamper awareness.

Dilemma 2 - Disease-specific guidelines versus standardization of hospital care

The use of standardized medical decision making should be increased within hospitals to reduce preventable harm.⁶ To prevent undesirable practice (it may harm patients), Dutch hospital boards of directors are responsible for the adoption and correct implementation of all quality standards within a hospital.¹⁹ As most guidelines are not harmonized at a national level, many hospitals are obliged first to solve any disagreeing requirements, before deriving standardized hospital protocols.¹⁹ However, recommendations in guidelines are often disease specific and, therefore, differ between professional groups treating different types of patients within one institutional setting. Also, when applying guideline recommendations, it is essential to consider patient values and preferences along with staff experience and expertise.²² If hospital boards are not able to oversee all guidelines and patient preferences, then they cannot be responsible for the standardization of care.¹⁹ In other words, guidelines facilitate the disease-specific standardization of care but could hamper standardization on the hospital level and if used rigidly hinder the individual response of hospitals to patients.

Dilemma 3 - Optimal care versus affordable care

Professionals in guideline committees define what they see as optimal care for a given group of patients, based on scientific evidence, professional expertise, patients’ preferences, and experiences, by describing recommendations for daily practices in guidelines. By using these guidelines, hospital professionals focus on the individual patient

and do not necessarily take the best outcome for all (hospital) patients into account. This process is referred to as a “deontological” enterprise.²³ However, in the “real world,” hospital boards and managers often need to make choices.²¹ These may be at odds with the optimal care described by a guideline committee.

For hospitals to improve the value of care and reduce waste, they have the responsibility to balance the delivery of care as outlined in the guidelines against the available resources in their organization.²⁴ This process of using finite resources in the best possible way is called utilitarian enterprise.²⁴ In essence, guidelines are often developed from a deontological point of view, without taking into account that they have to be implemented in a “utilitarian” framework. Guideline developers should not neglect this rationality, but facilitate it by grading the relative relevance of the recommendations.

Dilemma 4 - Guidance versus control

Guidelines should be seen as a reference tool to aid patient care.²² However, they are increasingly (being) used as reference standards for internal and external clinical audits, for pay for performance schemes, to negotiations with insurers, by the media and for medical lawsuits.⁷ Guidelines that were designed with the intention of keeping the knowledge of professionals concise and up to date are being used for broader purposes, for example, for control interests and enforcement measures. The question that arises, as a result, is how the original intention relates to the current and contemporary application in the field. For instance, Dutch hospital managers question whether the guidelines that are enforced by regulators are also the ones that reduce the most risk or contribute the most to quality improvement in a hospital.²¹ Hospitals differ in their strengths and weaknesses, and in the populations that they serve and therefore in the risks manifested in patient care. As described earlier, hospitals need a certain degree of autonomy to make choices that reflect the needs of their particular patient population and region. They need to be able to focus on specific topics that need quality improvement for which guidelines can offer valuable support. External control mechanisms, however, force hospitals to concentrate on some guidelines at the expense of other topics, which leads to a misfit

between internal and external demands.²¹ In other words, control should help hospitals to proactively focus on quality issues that need the most attention in their case.

Synthesis

Hospitals are vital stakeholders in the development and use of guidelines. One cannot exist without the other. Nonetheless, many hospitals worldwide struggle with the implementation of guidelines.^{4,7,25} To deal with the implementation struggle as described in dilemma 1 and dilemma 2, improvements in the process of developing and disseminating clinical guidance were proposed. Also, a new approach that is not only practical but also calls for a different approach is being looked for. First, it is important that representatives of hospitals are involved in the development process in the case of guidelines that (are expected to) make recommendations that have a profound impact on hospital budgets. For making the recommendations, the GRADE (Grading of Recommendations Assessment, Development and Evaluation) working group recommends two steps. The first is to consider whether the use of resources is important (or critical). The second step is to analyse the potential impact of the specific items of resource use on different strategies. They argue that in order to consider all the relevant resources and costs, “it is important that guideline developers include the relevant stakeholders and not just clinicians”.²⁶ Second, guideline developers should develop and use formats, for example, consisting of a standardized set of modules or building blocks, to enable users to compare recommendations across disease-specific guidelines quickly. Furthermore, in countries with decentralized development, some form of centralized dissemination would ease the burden on individual hospitals and other frequent users of guidelines. Improving recommendations and dissemination could enhance the guideline implementation in practice. So, practical adaptations that could certainly simplify matters for hospital boards and professionals are summarized in Box 7.1.

Practical:

- Involve hospitals in guideline development (dilemma 2)
- Use standardized sets of modules for guideline development (dilemma 3)
- Aim for centralized dissemination (dilemma 1)

Conceptual:

- Use guidelines for formative assessment mainly (dilemma 4)
- Accommodate summative assessment in limited priority areas based on risks for patients as assessed by guideline developers (dilemma 3 and 4)

Research:

- Choose the hospital as the unit of analysis when studying the implementation of clinical guidelines (dilemma 2)

Box 7.1 - Recommendations

However, the problem cannot be solved by a better organization and management of guideline development only. It was suggested that the ultimate goal is not guideline implementation and compliance. The authors are looking for a new way out that is not only practical but also calls for a different approach to be able to address dilemma 3 and dilemma 4. As stated in the “Introduction,” the original purpose of guidelines was to improve quality by making the evidence-based choice the easier choice. To accomplish this, an evolution return to a model in which guidelines are essentially used for learning (formative assessments) instead of control, rewards, and punishments (summative assessments) is advocated. The aim is to help to identify the strength and weaknesses of a hospital. This learning can create space for hospitals to determine together with their patients and professionals which improvements are needed. Using evidence, and therefore guidelines, helps to choose wisely. Shifting the focus to the learning capacity of hospitals and professionals may have a more favourable impact on health care quality than increased control using summative assessments. However, some limited forms of summative assessments may still be necessary for specific safety aspects. Guideline developers could help guideline users identify those aspects by clearly indicating which

recommendations should be seen as mandatory and motivate this by an assessment of the risks involved with non-compliance. The authors added the recommendations presented in Box 7.1 to simplify matters for hospital boards and professionals to the leaky evidence pipeline (Figure 7.1).²⁷

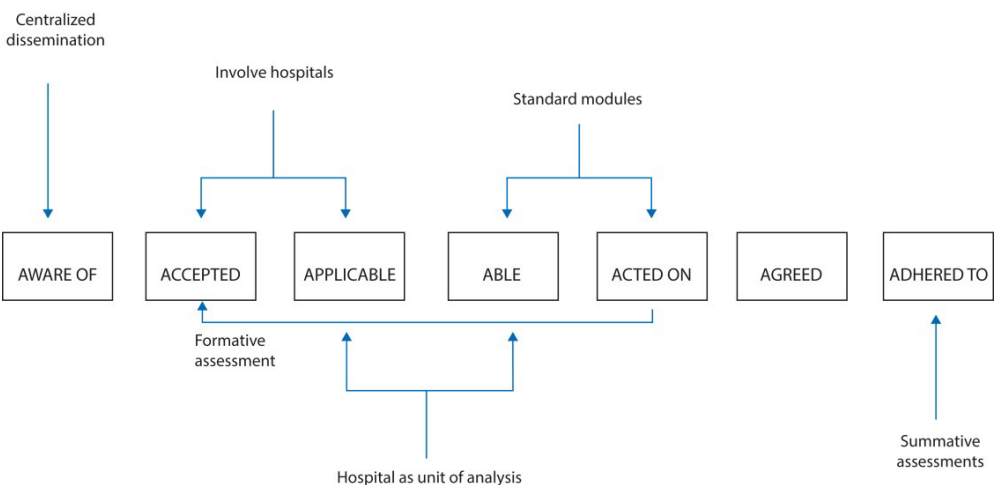


Figure 7.1 - A Process Outline

The recommendations can minimize the leaks that occur between the seven stakes of the pipeline. Finally, the authors call for different ways of studying the issue of guideline implementation. To date, research is about guidelines for professionals, and hospitals are merely the context. The emphasis should be on the cohesion between hospitals and the health professionals. It was advised that the hospital is the starting point instead of just the context of research. It should be the unit of analysis.

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Chapter 8

General discussion

In this thesis, we focussed on the use of guidelines and problems surrounding guideline implementation in hospitals. Guidelines are increasingly used for decisionmaking (processes) in health care practice and policy [1] and enforcement organisations also base their decisions on guidelines [2, 3]. The healthcare quality regulator in the Netherlands, the Health Care Inspectorate (IGZ), holds hospital boards of directors accountable for the quality of care delivered in their hospital and for managing the compliance with guidelines and other standards, norms, and regulations (summarised in this thesis as “external demands” on hospitals). However, the number of standards and guidelines in healthcare is large and changes at a fast pace. Guideline development and publication in the Netherlands is neither centralised nor standardised. Hence, for hospitals, there is uncertainty about what to adhere to [4, 5]. The aim of this study was to develop a strategy for how hospital boards realise compliance with guidelines and other external demands and to explore whether it is realistic to expect that these strategies succeed.

In the following, the main research findings of this thesis are summarised and reflected upon. The conclusions are summed up in Table 8.1. The first three studies were already partly discussed in Chapter 7. Supplementary discussions of the main findings are displayed and interpreted in this chapter. Additionally, methodological limitations are discussed, as well as implications for policy and practice.

Main findings and their interpretation

The **first study** describes in a case study how a hospital board managed external demands. In 2010, the hospital was placed under “enhanced surveillance” by the Inspectorate, as it did not comply with two guidelines. Interestingly, the hospital board and management were not aware of one of the guidelines. In the Netherlands, an overview of available and enforced external demands is missing and the dissemination is not well organised. Therefore, the hospital board initiated a thorough study and inventory of external demands so they could form a proactive approach for responding to such regulations. To coordinate compliance, the hospital created a database of the requirements. The study showed that the database was a helpful tool for tackling the lack of overview. Being unaware of guidelines is a broader problem that occurs in other countries, too, and is

caused by the amount of guidelines and unstructured distribution. In countries such as the United States, Canada, and the UK, the number of guidelines has also increased [6]. The way the Inspectorate uses guidelines is not unique to Netherlands, as what might seem as a recommendation can easily be viewed in court as mandatory in other countries as well [6].

The study also showed that it is challenging to keep the database up-to-date. External demands are constantly improving and standards are rising [7]. Other countries struggle with guideline implementations as well and lack of awareness, lack of familiarity, and access to guidelines are among those barriers restricting guideline implementation [8-10]. Fischer (2016) and Sola (2014) suggest that the awareness and knowledge of guidelines are the first strategies to overcoming those barriers [8, 11]. Interestingly, awareness and lack of familiarity were already described as a barrier back in 1999 [12]. The attempt to facilitate an overview in this study might be one of many possible strategies to enhance awareness of guidelines to finally, eventually enhance implementation.

The **second study** in this thesis examined whether hospitals can benefit from the database, which was described in the first study, and from the so-called risk-based prioritisation system, developed in Zuyderland MC. The second study also addressed whether other Dutch hospitals were subject to similar problems. The findings revealed that participating hospitals experienced great difficulties in coping with a lot of external demands. Furthermore, results displayed that the infrastructure for meeting external demands in Dutch hospitals need to be arranged more effectively in order to meet external demands. This is in line with previous findings [13]. Other research shows that redundant information that is delivered in an uncoordinated and in an ineffective manner creates information overload [14] and that many guidelines do not adhere to the standard from the Institute of Medicine [15, 16]. Some authors even claim that guidelines cannot be trusted [17]. Literature shows that hospital boards have insufficient information for decision-making to address health care policy challenges [18, 19]. In our study, the database and the risk-based scoring system were assessed useful by participants for prioritising external demands on a local level. Our study showed that hospital boards cannot comply with all guidelines and suggests that a database with all external demands

and risk-based implementation is a viable option for hospitals to help identify and to choose priorities in compliance management wisely. Guidelines that incorporate ineffective recommendations need to be de-implemented in order to allow hospitals to use the resources for other purposes and to minimise harm and inefficient practices, according to research [20]. Therefore, the results of this study can help to master the challenges of de-implementation, as prioritisation based on risks can help evaluate the benefits of implementation and de-implementation at the same time. The method applied in Zuyderland MC may help to master the challenges of de-implementation because it facilitates hospital boards in responding to and managing broader political, social, and contextual factors that need to be taken into account [21]. Until the present moment, an optimal approach to master de-implementation is not known, but increased attention is given to the issue [20, 22-24].

The **third study**, included in this thesis, examined whether Dutch hospital boards perceived problems in their guideline adherence, how boards arranged responsibilities for adherence, and which options boards identified as appropriate improvements. In the Netherlands, hospital boards are responsible for the financial and health care performance of their hospital (i.e. quality of care). Medical specialists have a share in this responsibility. However, what this exactly entails is not clearly defined and is not always translated into practice [25]. The third study showed that arranging responsibilities and verifying adherence is challenging for boards of directors. Participants reported that an overview of available and enforced guidelines was lacking. The results of this study recommend a shift in the distribution of responsibility, as in a more desirable situation, the ultimate responsibility of the board of directors would decrease and the responsibility of the medical specialists would increase. To realise this shift, hospital boards are dependent on what is expected of them in terms of quality of care. Our study showed that guidelines received more attention if they were strictly enforced by the Inspectorate, which shows that external pressures can play an important role in the prioritisation by the hospital boards [26]. Recently, the new Dutch Governance code was published [27] and the basis for good governance and supervision in health care organisation is still the same as in 2010; however, the approach is shifting from one of following checklists for the sake

of the rules, towards a deeper understanding of the intentions of the rules. This is in line with our finding that respondents expressed a need for a clearer distinction between (parts of) guidelines that are enforced and (parts of) guidelines that aim to provide guidance for professionals. Currently, there is a gap between what is seen as desirable and what is actually feasible: 97% of respondents thought that it was important to adhere to guidelines, while only 42% agreed that it was feasible. Our study showed that the participants think that a central national database/portal with all updated guidelines is a possible solution to avoid duplication, to reduce the number of guidelines, to determine what is valid and invalid, and to allow prioritisation based on the risks for quality of care.

The findings of this **third study** are in line with the findings of the **first and second study**. Until now, hospitals have largely relied on individual professionals to ensure that patients receive treatment according to guidelines. The literature suggests however, that the creation of a system (e.g. with the use of technology) by hospitals and guideline developers that facilitates the implementation process for professionals would result in fewer barriers to guidelines [28].

The results of our study can be helpful in reconsidering whether the emphasis should be on learning and improving instead of enforcement and legislation [29, 30]. Furthermore, it can help to discuss whether research needs to widen the focus from hospitals to the health care system at large since the hospital is only a part of the much larger health care system.

In the **third study**, most hospital boards (59%) reported that they have problems with the use and responsibilities for implementation of guidelines in their hospitals. However, a few hospital boards reported that they do not experience problems with the implementation of guidelines in their hospitals. In the **fourth study**, we conducted interviews with three of those hospitals that have no problems with implementation, in order to achieve insight into how Dutch hospitals can ensure that guidelines are used in practice, and to identify what other hospitals can learn from them. The study showed that these “best practice” hospitals find guidelines useful and necessary. Participants mentioned that the use of guidelines can be enhanced if: boards of directors and medical staff cooperate with each other, are committed, intrinsically motivated, and use guidelines

pragmatically. If resources are scarce, these hospitals prioritise guidelines. Apart from that, these hospitals focus on integrating guidelines into their own policies. This is in contrast to the hospital boards who did report experiencing problems with guideline implementation. Their focus was to a much greater extent on external expectations, leading to defensive behaviour. Bero (1999) showed that the passive dissemination of information limits its effectiveness [31], while active implementation of research findings into clinical practice increases the applicability of research and increases the chances of adherence [32-34]. The use of guidelines in practice requires more than robust and believable evidence [33]. The leadership of professionals and commitment are needed to implement guidelines in practice, as implementation requires the most energy [34]. A pragmatic approach of guidelines contributes to the positive perception of professionals and may contribute to close the gap between research and clinical practice [11]. Although guidelines are intended to optimise patient care [35] and are increasingly used for decisionmaking (processes), guidelines are often not used in practice, let alone implemented. Knowledge brokering can bridge the research-to-practice gap, translating guidelines to the local context [36, 37]. Knowledge brokering can be used to influence the use of guidelines in practice, with the potential to improve health outcomes [38]. This is necessary, as optimal care is not a direct consequence of guideline implementation and adherence [39]. However, through brokering, guidelines are translated into practice across different hospital layers [40]. This study shows participants from hospitals who say that they do not have problems with implementation indicate that the following factors improved guidelines implementation in their setting: being committed to guidelines, being intrinsically motivated to understand and use guidelines, cooperation between boards of directors and medical staff to get research into practice, and a pragmatic approach towards using guidelines. This basically summarises what knowledge brokers do [41]. Knowledge brokering can be used to adapt guidelines by individuals, but it can also be applied by organisations such as hospitals [42].

In the first four studies, we concentrated on the board of directors viewpoint on guidelines. As stakeholders around hospitals affect the daily challenges a hospital faces, the **fifth study** focussed on identifying what external stakeholders could do to help

hospitals cope with norms and guidelines. This study showed that norm developers, norm enforcers, and norm users acknowledged that problems with implementing guidelines in hospitals do exist. Norm developers, norm enforcers, and norm users confirmed that the “system of guidelines” neither assists professionals adequately, nor does it share the hospitals’ sense of urgency for improvement. Our study showed that participants reported that norm producers can help by indicating: the target (group) of the recommendations in the guideline, the imposed obligation, and the purpose of a norm/guideline/indicator. The study also showed that an enhanced IT infrastructure would be helpful. Norm producing institutions could deliver guidelines and indicators in an easily accessible way (website and app), which would also be easy to integrate into hospitals’ IT support systems. Existing barriers can be overcome and the impact of guidelines for high- and low-value care can increase if guidelines are available at the point of care, embedded in a user-friendly way into electronic health records [22, 43]. Even though several organisations are engaging in guideline improvement and guideline development has become more professional [16, 44, 45], only few guidelines adhere to the key standards so far [46]. An innovative research programme in Norway (MAGIC, Making GRADE the Irresistible Choice) offers practical solutions for the development, creation, dissemination, update, and facilitation of shared decision-making. Two of these practical tools are “Structured and tagged content created in an online authoring and publication platform to allow dissemination in a wide range of devices: web platforms, applications for tablets and smartphones, and integration in EMRs” and “Electronic decision aids, linked to recommendations in guidelines, for use by clinicians and patients in consultations” [46]. These relate to potential solutions that were suggested in the focus group discussions of our study.

The **dilemmas** described in Chapter 7 lead to the idea that guidelines should rather be used for learning instead of control. The original purpose of guidelines was to make the evidence-based choice the easier choice; however, guidelines are increasingly being used for enforcement. Disciplinary measures can lead to cautious and defensive practices by professionals [47]. The Inspectorate noticed that it “seems a promising strategy” to focus on improving and learning in the context of incident reporting systems. It would be interesting to conduct further research to find out whether the focus on improving and

learning instead of non-compliance and failure [4] will also be a good strategy for guidelines. The Inspectorate has announced a shift in their approach to supervision by applying more nuance in their judgements [48].

Table 8.1 - Conclusions

	Name study	Problem statement	Conclusion
1	How to manage external demands in hospitals – the case of Atrium MC	What is the feasibility of adhering to external demands and effective management by hospital executive boards of compliance with clinical guidelines?	A national overview of external demands is needed to enhance awareness of guidelines to finally eventually enhance implementation.
2	Optimal use of external demands in hospitals – a Delphi study from the Netherlands	Can a risk-based prioritisation system help hospitals cope with the pressures of external demands?	Hospital boards cannot comply with all guidelines. A database with external demands and risk-based implementation is a considerable option for hospitals to help identify and choose guidelines wisely.
3	Guideline adherence: How do boards of directors deal with it? A survey in Dutch hospitals	Do Dutch hospitals experience challenges in complying with medical guidelines and what are possible difficulties and opportunities for improvement?	In a more desired situation the ultimate responsibility for guideline implementation of the board of directors would decrease and the responsibility of the medical specialists would increase.
4	What Hospitals Need to Know About Guidelines – A Mixed-Method Analysis of Guideline Implementation in Dutch Hospitals	How do these hospital boards ensure that guidelines are used in practice, and how do they minimise ‘leaks’ in handling compliance?	Being committed to guidelines, intrinsically motivated to understand and use guidelines, cooperation with each other to get research into practice and using guidelines pragmatically would likely improve implementation of guidelines.

- Table 8.1 continued –

	Name study	Problem statement	Conclusion
5	The inherent perils of (the multitude of) guidelines– a focus group study of stakeholders perceptions	<p>More specifically, we looked at</p> <ul style="list-style-type: none"> • what producers of norms and guidelines for hospital care can do to reduce the amount of guidelines/norms and improve the clarity and consistency? • what norm-enforcing institutions can do to focus and align priorities and reduce uncertain-ties for hospitals about what they are expected to comply with? • what hospital boards, managers and staff can do to successfully integrate norms and guidelines into hospital systems? 	<p>This research showed that hospitals must join forces to become an active player in the process of guideline development. Together, stakeholders should combine their efforts to optimise the chain of guideline production, use and enforcement at the healthcare system level. Participant's believe that implementation is not only the responsibility of hospital boards and professionals and suggest that the responsibility distribution for guideline implementation should be adjusted.</p>
6	Good intentions getting out of hand – is there a future for healthcare guidelines?	Good intentions getting out of hand – is there a future for healthcare guidelines?	Focus on improving and learning instead of noncompliance and failure

Limitations

The studies in this thesis focused mainly on hospital boards, quality and safety managers, and stakeholders and their perspectives rather than on measuring the effects of guidelines on patient outcomes and safety. We did not study whether the use of guidelines actually leads to better compliance or not, or how guidelines are used in the workplace. In addition, we did not measure if quality of health care is related to the stakeholder's perception of guidelines. We used different methodologies thereby diminishing the chances of selection bias. Of course our participants predominantly represented the

managerial and governance perspective, not focussing on the perspective of the practising clinician. However, we were unable to examine which extent the participants were representative of all Dutch hospital boards. Another possible limitation is that the authors are researchers and at the same time, they work in the field of study: JB, NvW and LB work in different positions in the hospital sector and DD works for the National Health Care Institute. In theory, this could have been a source of bias or led to conflicts of interest. However, as a research team we mitigated this by repeatedly and explicitly addressing this issue in our discussions about the interpretation of the results. In doing this, it was helpful that all the team members looked at the research from very different perspectives: LB and NvW from the hospital quality and safety department perspective, JB from the perspective of a practising physician and DD from the national and public perspective.

Implications for Policy and Practice

Quitting smoking is difficult for some smokers, because the positive impact of cessation is not immediate, and the benefits occur after a long period of time. This can also be true for guidelines: the implementation involves capacity, financial resources and -often- behavioural change, whereas the benefits to patients are not always directly visible. This is one of the several reasons why it is not easy to increase the use of guidelines in practice. Another reason is that the development, the use, the implementation and the benefits occur on different levels. Guideline developers (medical en non-medical) are not the only ones who have to use and implement them on a daily basis. The same analogy exists between the one implementing the guideline and the patient. Not implementing a guideline has often no direct consequence for the one providing health care. Keeping this in mind, there are several policy and practice implications, which we grouped into three topics.

1. Actors improve their own work

At present, actors work mostly within their own systems: guideline developers in the system of producing and disseminating guidelines, the Inspectorate in the system of surveillance, and hospitals in their system of implementation (Figure 8.1).

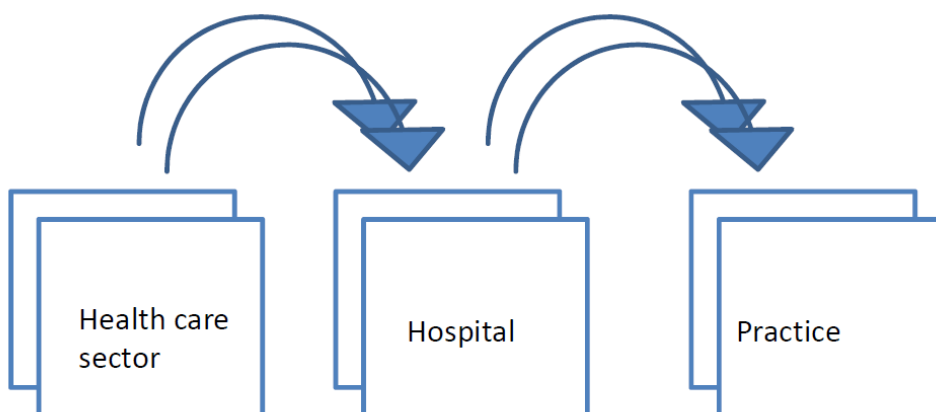


Figure 8.1 – Current system

Our studies show that there is room for improvement within these systems (Chapter 2,3,5,6). For example, guideline developers should harmonise and standardise production and distribution of guidelines, keep in mind that other parties also impose guidelines on guidelines users and bear in mind that developed guidelines can also be used for enforcement purposes. The allocation of responsibilities for the guideline recommendations should be clear, as well as the level of obligation: is it obligatory/ optional/ advisory? Guideline developers should use knowledge of (potential) guideline users to include elements such as the purpose of the norm/guideline/indicator, as well as the responsible target group, and a time frame for implementation (Chapter 6). At the same time, hospitals can influence guideline development through participation and co-creation, be aware of the production and organise the distribution of guidelines, set stepwise priorities if they cannot implement all guidelines at once, commit to the purpose

of guidelines and find and use intrinsically motivated staff to enhance the implementation of guidelines (Chapter 5).

2. Transition to joint improvements

At present, the interaction in terms of collaboration and feedback loops between the actors is limited and the improvement strategies mostly focus on one of the systems: the guideline developers try to improve their guidelines and hospital boards try to enhance compliance. The results of our studies lead to the idea that forces must be bundled to increase the implementation of and adherence to guidelines (Chapter 3,6). Actors should create and maintain a collective vision and agree on collective improvements. Provided that the use of guidelines to close the gap between science and practice is the desired aim, actors should install feedback loops and consider the context (Figure 8.2).

Norm users and the norm enforcers do similar work as soon as a guideline is published: they study the guideline and its requirements and examine the impact: what is mandatory and needs to be implemented (norm user) or supervised (norm enforcer)? An implementation table in each guideline could provide clarity for the different users, the expectations and the time frame. If guideline developers could integrate these elements, administrative hassles could be reduced. Recently, a guide was created for the translation process from external demands for supervision and for the evaluation of enforceability of external demands by structured cooperation and communication [49]. This offers opportunities for efficiency gains in the steps that lead to the implementation of guidelines as rules.

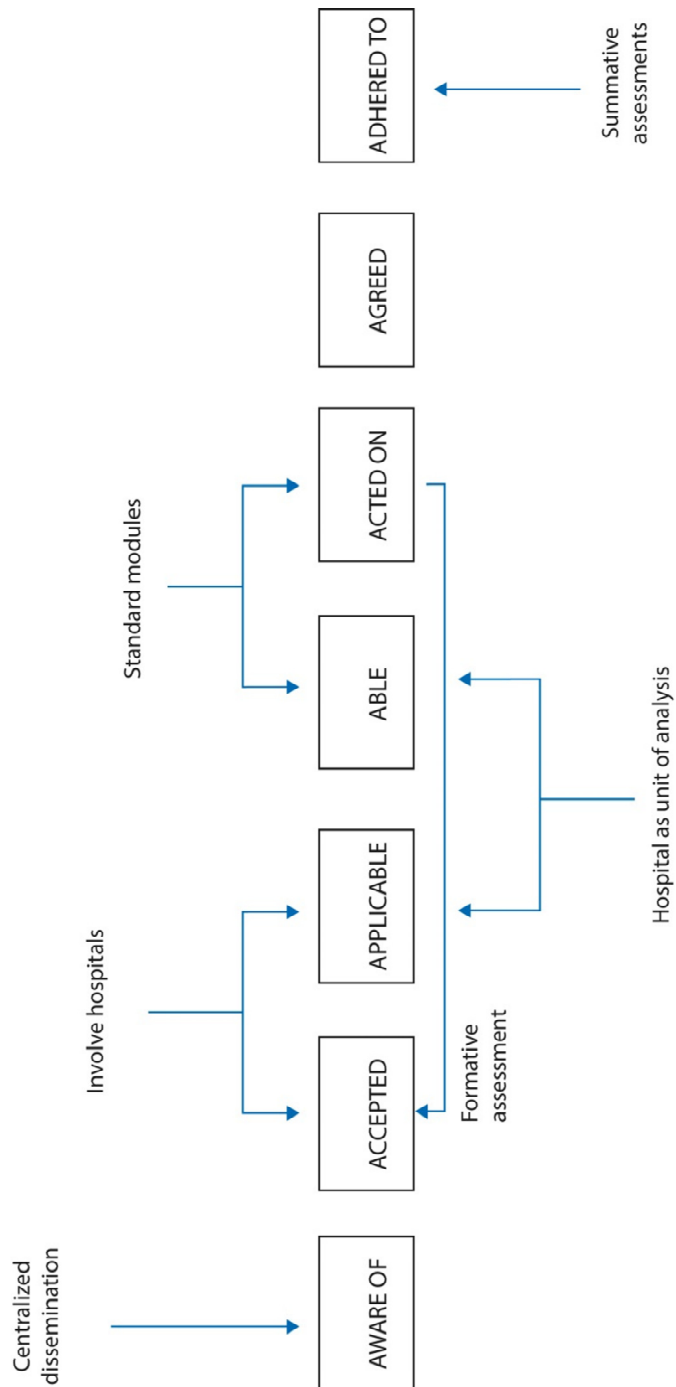


Figure 8.2 – Incorporating context and learning

3. Learning on three levels

A shift is desirable from enforcement to learning: “Learning where needed, enforcement where inevitable”, should be the motto. Learning can occur on three levels (Figure 8.3). On the first level (in practice), a feedback loop can initiate change, if professionals reflect on their results. Guidelines can be used as applicable tools to do so, as you can organise quality instead of compliance. Furthermore, professionals can provide feedback to either the guideline developer or the hospital board, if the implementability of guidelines can be improved. On the second level (hospital), the use of guidelines can be influenced by the hospital boards, if they find guidelines useful and create a link between these guidelines and their own processes. This requires boards of directors and medical staff who are committed, intrinsically motivated, cooperate and use the guidelines pragmatically. Setting priorities helps to master the situation. The hospital has therefore a feedback loop with the first level, but also the third level (health care sector). On the third level, knowledge brokerage can be used to enhance the knowledge transfer between guideline developers, enforcement agencies and guideline users. Collaborations between hospitals and actors could increase the accessibility and implementability of guidelines. A possible idea is a collective practice which focuses on the three learning levels: clinical setting, hospital, healthcare system level (Figure 8.3). Further research is needed whether this could enhance guideline use, leading to better care.

One possible contribution to facilitate the guideline dissemination, use, and implementation can be found in the application of IT solutions. On level one and two, a good IT-directed guideline support system could enhance guideline use, implementation and adherence in practice, where requirements of guidelines are integrated into the clinician’s workflow and medical records [50]. Evidence indicates that it can contribute – good examples can be found in Norway [46] and in the Dutch general practice.

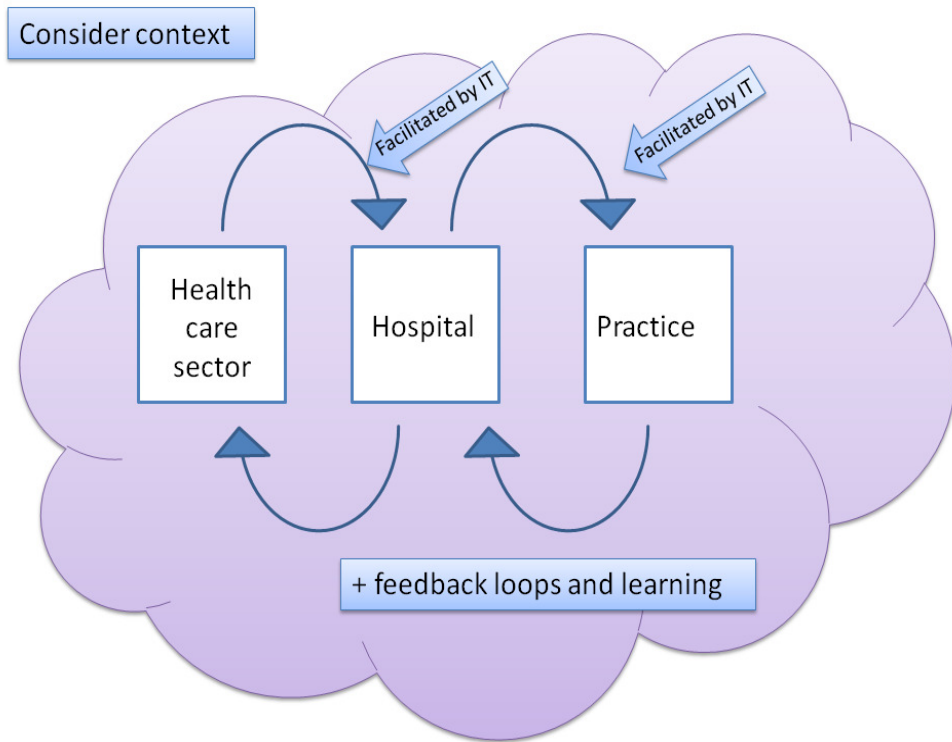


Figure 8.3 – Learning on three levels

Vandvik (2013) describes the Norwegian approach: “We have developed an online application that constitutes an authoring and publication platform that allows guideline content to be written and structured in a database, published directly on our web platform or exported in a computer-interpretable language (eg, XML) enabling dissemination through a wide range of outputs that include electronic medical record systems, web portals, and applications for smartphones/tablets.” [46]. It would be interesting to investigate whether the Norwegian approach could be cross pollinated to possible approaches for the Netherlands. The Norwegian approach makes the guidelines available at the point of care and supports the health care delivery. In this approach, the focus is on guidelines as a tool. It would be necessary to connect the requirements from guidelines (level 3) to work sequences (level 2) so that recommendations in guidelines can

be easily accessed at the point of care delivery (level 1). A possible starting point to test this approach could be specialism related guidelines.

Another example are the GPs in the Netherlands. Since 1989, more than 100 evidence-based guidelines were produced by Dutch college of general practitioners, and they are regularly updated (www.nhg.org). GPs have computer decision support and the guidelines are targeted at and developed by GPs, using the AGREE tool. The guidelines are all summarised in one page (<https://www.nhg.org/nhg-standaarden>) and the developers also make the information available via a website which can be consulted for free: www.thuisarts.nl. However, this is only a partial possible solution, as GPs have a fraction of the number of guidelines a hospital has to be aware of. An IT solution is one of the possible recommendations, and further research is necessary to determine what the scope of this solution can be.

8.3 Concluding remarks

This thesis shows that full compliance with guidelines by hospital boards is a “mission impossible”. Realising that hospitals face several challenges while they try to cope with guidelines and external demands, contributes to our understanding that guideline compliance is not the ultimate goal. The ultimate goal is quality and safety in hospital care, with relevant outcomes for patients. To cope with the complexity of guideline implementation, the focus should be on improving and learning instead of noncompliance and failure. Hospitals need to commit to guidelines and use them pragmatically to continuously improve health care. Further research is needed whether IT solutions and knowledge brokering could enhance guideline use. The work has raised the question whether strict guideline enforcement is the way to go. The results suggest that enforcement should be narrowed down to several requirements all actors can access and agree on. Further research should examine the use of guidelines in hospitals, as a setting in which multiple professional guidelines have to be implemented simultaneously, and in which clinical guidelines have to be aligned with other external demands.

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English summary

Guidelines and systematic reviews sum up the available scientific knowledge to support the decision-making processes in patient care. The overall attitude towards guidelines as tools to achieve effective and efficient care is positive (Farquhar, 2002). However, guidelines can still be improved, as they lack standardisation and face implementation barriers. Several collaborative efforts on national level were set up to overcome the obstacles faced. The publication of guidelines does not automatically lead to implementation and evidence for successful strategies are sparse. Therefore, stakeholders need to focus on the challenges of implementation. Even though guideline development and implementation is an ongoing process, guidelines have increasingly been used as benchmarks for decision-making in health care practice and policy. In the Netherlands, hospital boards are held accountable for the implementation of guidelines and compliance management. However, there are a large numbers of guidelines in existence, with changes occurring at a fast pace a lack of systematic dissemination. Therefore, hospital boards often struggle with what is expected of them with regards to implementation.

The aim of this thesis was to acquire insight into how hospital boards realise guideline compliance and whether it is realistic to expect that this succeeds. A better understanding of the challenges for guideline implementation from a hospital board viewpoint may contribute to handling guidelines in a hospital setting, to developing more effective guideline implementation plans and ultimately, improving patient care. The thesis addresses the following research objectives:

1. To assess how hospitals cope with guidelines and other external demands
2. To explore possible solutions that help hospital boards cope with norms and guidelines within their hospitals

Chapter 2 describes how a Dutch hospital manages external demands and discusses what other hospitals can learn from their approach. In all modern healthcare systems, it is difficult for hospitals to keep pace with the increasing number of guidelines. This poses a specific problem in the Netherlands, as the national quality regulator holds hospital boards responsible for compliance with guidelines. At the same time, there is no overview

of applicable external demands and the dissemination of relevant guidelines is not well-organised. The hospital under study addressed this problem by constructing a centralised database for its guidelines. Due to the enormous number and the inter-relatedness of the guidelines, this task was larger and more complex than anticipated. This raised questions regarding the feasibility of adhering to external demands and concerning effective management by hospital boards of compliance with guidelines.

The results of the study described in **Chapter 2** led to an intended collaboration between a few hospitals. The suggestion was to first introduce and then test an appraisal of the relevance of external demands for hospital management based on risks. This was done in the study described in **Chapter 3**.

In **Chapter 3**, the results of a Delphi study are described. We investigated whether a risk-based prioritisation system can help hospitals to cope with the pressures of external demands. Regulatory authorities focus on promoting compliance of hospitals with a variety of external demands. Due to the amount of these external demands, hospitals may have to prioritise the external demands. In this study, we explored to what extent a risk-based prioritisation system developed by one Dutch hospital is applicable in other hospitals as well. We conducted a Delphi study containing three rounds with seven quality and safety managers. All participants were experienced in coping with external demands in Dutch hospitals in general and their own hospital specifically. These experts were granted access to a sample selection of a database containing about 1500 external demands. Prior to the Delphi study, a baseline measurement was carried out where all participants answered open-ended questions aimed at identifying existing practices, possible challenges concerning external demands and to prepare the survey for the group Delphi study. A high level of consensus was identified during the study. The results showed a high level of consensus during our Delphi research. The participants agreed that at present, Dutch hospitals do not cope with external demands systematically and that the infrastructure for external demands in Dutch hospitals needs to be arranged more effectively. Participants indicated that if the expectations were defined more precisely, external demands can be addressed more efficiently and compliance could be improved. The study showed that working on the database jointly with other hospitals could be

useful and that regular exchange between hospitals is desirable to discuss high priorities and national developments. The database and the risk-based prioritisation system are useful tools to cope with the amount of external demands and respondents indicated that they would also like to use these tools themselves in the future.

On the basis of the results described in **Chapter 3**, we investigated how boards of directors deal with guideline adherence. The results of the survey study are described in **Chapter 4**. A survey was sent to 116 Dutch hospitals in 2015. Thirty-nine responses were included in the study for further analysis (net response rate of 36%). All data other than the open questions were analysed in SPSS, using descriptives to answer the research question. The results show how boards of directors of general and specialist hospitals arranged the responsibilities for guideline adherence within their organisation, how boards of directors deal with guidelines for medical specialists and what opportunities exist for improvement. Despite the importance of guideline adherence, the respondents experienced problems on that matter. Adherence to guidelines was often reported to be low, as multiple barriers exist for guideline implementation. The findings of the survey demonstrated that the distribution of responsibility concerning guideline implementation is problematic. Hospital boards are responsible for the adoption of all quality standards, however, participants experienced challenges in arranging responsibilities for adherence within their organisation. Participants used a variety of information sources to keep informed about the status of implementation of the guidelines for medical specialists, mostly through medical specialists' external peer reviews (visits) and internal audits. While almost all participants stated that it is important that hospitals adhere to the guidelines for medical specialists, only 42% stated that this is feasible. The study revealed several opportunities for improvements, for example, that a national database is necessary with all up-to-date guidelines, whereby, changes and news are distributed directly to hospitals and other stakeholders. This study led to recommendations for a thoughtful shift in distribution of responsibility, as in a more desired situation the ultimate responsibility of the board of directors would decrease and the responsibility of the medical specialists would increase.

The results from **Chapter 4** showed that few hospitals reported that they are not having problems with the implementation of guidelines in their hospitals. We decided to conduct in-depth interviews with three of the hospitals that did report not to have problems, to learn how these hospitals ensure that guidelines are used in practice and identify the key messages from which other hospitals can learn.

In **Chapter 5**, we looked at current practices in handling compliance and therefore focused on hospitals which reported that they do not experience problems in the implementation of guidelines. We used additional data from the survey with Dutch hospital boards and nine semi-structured interviews with a purposive sample of three hospitals. Interviews were held with three representatives of each hospital, namely with a member of the board of directors, a member of the hospital board of the medical staff and the manager quality and safety. After analysing the interviews, themes that emerged in relation to the implementation of guidelines in the hospitals were cooperation, commitment, hospital size, utility of guidelines, intrinsic motivation and barriers to guideline adherence. Cooperation between the medical staff and the hospital organisation was reported to be important for the implementation of guidelines. Respondents indicated that the size of the hospital is relevant, as - according to them - implementation is easier in smaller hospitals. Respondents showed commitment and searched for the purpose behind the rule. Respondents ensured that the requirement is appropriately calibrated to the internal policies, if guidelines hinder or are not applicable in the hospital situation. Despite their good work, all hospitals struggled to adhere to guidelines. The hospitals found guidelines necessary and useful and had the power to improve implementation if boards of directors and medical staff were committed, intrinsically motivated, cooperate and use guidelines pragmatically. They prioritised their guidelines, if resources were scarce. If hospitals experienced problems with guideline implementation, they tended to focus more on external expectations, leading to defensive behaviour, while hospitals that did not experience implementation problems focused more on integrating guidelines into their own policies.

In **Chapters 2 through 5**, we focused on the responsibilities of the board of directors for guidelines: The question we asked included what kind of problems do hospitals

experience, how do they experience their responsibility with guidelines, how do they take note of what is expected from them, how do they invest in the tasks of their organisation? Having addressed these primary research questions however, we set out to broaden our focus, by not only looking at the hospital organisation as unit, but looking at the hospital as a part of a whole chain.

Chapter 6 describes the results of focus groups, presenting possible strategies for all hospitals and their stakeholders concerning the use of guidelines. During the focus groups, we wanted to identify possible strategies that address the whole chain of guideline and norm production, use and enforcement, which could help hospitals boards and management to cope with norms and guidelines. Therefore, we performed a qualitative study consisting of three focus groups involving a total of 28 participants. Three themes emerged from the results and showed that norm producers, norm enforcers and norm users acknowledged the problems that hospital boards face in keeping track of and implementing guidelines.

Several concrete solutions were proposed, such as: clear description of the division of tasks within guidelines, clarity about the purpose of guideline recommendations, a maximum number of quality indicators for hospitals and implementation of an ensuring proper Information Technology (IT)infrastructure. Summing up, the results of the focus groups showed that hospitals must join forces to become an active player in the process of guideline development. Together, stakeholders should combine their efforts to optimise the chain of guideline production, use and enforcement at the healthcare system level. Participant's believe that implementation is not only the responsibility of hospital boards and professionals and suggest that the responsibility distribution for guideline implementation should be adjusted.

Chapter 7 describes dilemmas we came across in the studies described in **Chapters 2 through 5**, where we identify the problems with the implementation of guidelines from the hospitals' perspective. We found that decentralised development of guidelines may increase acceptance but hamper awareness. Guidelines facilitate the disease-specific standardization of care but could hamper standardization on the hospital level. If used rigidly, guidelines can hinder the individual response of hospitals to patients. Guidelines

are often developed from a deontological point of view, where professionals focus on the individual patient and do not necessarily take the best outcome for all (hospital) patients into account. However, guidelines have to be implemented in a "utilitarian" framework, where finite resources have to be used in the best possible way. Guideline developers should not neglect this rationality, but facilitate it by grading the relative relevance of the recommendations. We found that control should help hospitals to proactively focus on quality issues that need the most attention in their case. We concluded that to return to the original purpose of guidelines (to make the evidence-based choice the easier choice), we advocated a return to a model in which guidelines are essentially used for learning (formative assessments) instead of control, rewards, and punishments (summative assessments).

In **Chapter 8**, we summarize the findings of the thesis and reflect upon those with the literature. The results of this research show that full compliance with guidelines by hospital boards is a "mission impossible". Realising that hospitals face several challenges while they try to cope with guidelines and external demands, contributes to our understanding that guideline compliance is not the ultimate goal. The ultimate goal is quality and safety in hospital care, with relevant outcomes for patients. To cope with the complexity of guideline implementation, the focus should be on improving and learning instead of noncompliance and failure. Hospitals need to commit to guidelines and use them pragmatically to continuously improve health care. Further research is needed whether IT solutions and knowledge brokering could enhance guideline use. The work has raised the question whether strict guideline enforcement is the way to go. The results suggest that enforcement should be narrowed down to several requirements all actors can access and agree on. Further research should examine the use of guidelines in hospitals, as a setting in which multiple professional guidelines have to be implemented simultaneously, and in which clinical guidelines have to be aligned with other external demands.

Nederlandse samenvatting

Richtlijnen en systematische reviews vatten beschikbare wetenschappelijke kennis samen met als doel de besluitvormingsprocessen in de patiëntenzorg te ondersteunen. De algemene houding is positief ten aanzien van richtlijnen als instrumenten om effectieve en efficiënte zorg te bereiken (Farquhar, 2002). Richtlijnen kunnen echter nog verbeterd worden, omdat er gebrek is aan standaardisatie. Ook zijn er implementatie barrières aanwezig. Op nationaal en internationaal niveau worden verschillende gezamenlijke inspanningen gedaan om de hindernissen uit de weg te ruimen, want de publicatie van richtlijnen leidt niet automatisch tot implementatie en het bewijs voor succesvolle strategieën is schaars. Daarom moeten belanghebbenden zich richten op de uitdagingen van implementatie. Hoewel richtlijnontwikkeling en implementatie verre van 'klaar' zijn, worden richtlijnen steeds meer gebruikt als benchmarks voor besluitvorming in de gezondheidspraktijk en -beleid. In Nederland wordt het ziekenhuisbestuur verantwoordelijk gesteld voor compliance management en de implementatie van richtlijnen. Echter, het aantal richtlijnen is groot, wijzigingen vinden in een snel tempo plaats en worden niet systematisch meegedeeld. Daarom worstelen ziekenhuisbestuurders vaak met wat er van hen verwacht wordt. Het doel van dit proefschrift was inzicht te verkrijgen in hoe ziekenhuisbestuurders compliance organiseren en of het realistisch is te verwachten dat dit lukt.

Het in kaart brengen van de uitdagingen met betrekking tot richtlijn implementatie vanuit het oogpunt van ziekenhuisbestuurders kan bijdragen aan een slimme omgang met richtlijnen, het ontwikkelen van effectievere richtlijn implementatieplannen en het verbeteren van de patiëntenzorg. Het proefschrift richt zich op de volgende onderzoeksdoelstellingen:

1. Om te beschrijven hoe ziekenhuizen omgaan met richtlijnen en andere externe eisen
2. Om mogelijke oplossingen te onderzoeken die ziekenhuisbestuurders helpen om te gaan met normen en richtlijnen binnen hun ziekenhuis

Hoofdstuk 2 beschrijft hoe een Nederlands ziekenhuis externe eisen beheert en betoogt wat andere ziekenhuizen kunnen leren van hun aanpak. Het is moeilijk voor ziekenhuizen om het snel stijgende aantal richtlijnen goed bij te houden. Dit vormt speciaal een probleem in Nederland, aangezien de Inspectie voor de Gezondheidszorg (IGZ) het ziekenhuisbestuur verantwoordelijk stelt voor de naleving van de richtlijnen. Tegelijkertijd is geen overzicht van de externe eisen beschikbaar en is de verspreiding van relevante richtlijnen niet goed georganiseerd. Het onderzochte ziekenhuis heeft dit probleem aangepakt door een gecentraliseerde database op te stellen voor de geldende richtlijnen. Vanwege het enorme aantal en de onderlinge verwantschap van de richtlijnen was deze taak groter en complexer dan verwacht. Dit leidde tot de vraag of het ziekenhuisbestuur de naleving van richtlijnen effectief kan inrichten en of het überhaupt haalbaar is de externe eisen na te leven.

De resultaten van de studie beschreven in **hoofdstuk 2** hebben geleid tot een voorgenomen samenwerking tussen een aantal ziekenhuizen. De suggestie was om een tool aan te bieden en daarna te beoordelen of hiermee de relevantie van externe eisen voor ziekenhuisbestuurders op basis van risico's kan worden beoordeeld. Dit gebeurde in de studie beschreven in **hoofdstuk 3**.

In **hoofdstuk 3** worden de resultaten van een Delphi studie beschreven. We hebben onderzocht of een risico gebaseerd prioriteringssysteem ziekenhuizen kan helpen om de druk van externe eisen aan te kunnen. Regelgevende instanties richten zich op het bevorderen van de naleving van een aantal externe eisen bij ziekenhuizen. Door de hoeveelheid externe eisen kan het nodig zijn voor ziekenhuizen prioriteiten te geven aan bepaalde externe eisen. In deze studie hebben we onderzocht in hoeverre een door een Nederlands ziekenhuis ontwikkeld risico gebaseerd prioriteringssysteem ook in andere ziekenhuizen van toepassing is. We hebben een Delphi studie uitgevoerd van drie rondes met zeven managers kwaliteit & veiligheid. Alle deelnemers ervaren problemen in het omgaan met externe eisen in het algemeen maar ook in hun eigen ziekenhuis specifiek. De deskundigen kregen toegang tot een selectie van de database met ongeveer 1500 externe eisen. Voorafgaand aan de Delphi studie werd een basismeting uitgevoerd waarbij alle deelnemers openstaande vragen beantwoordden die gericht waren op het identificeren

van bestaande praktijken, mogelijke uitdagingen met betrekking tot externe eisen en om de surveyvragen voor de Delphi studie voor te bereiden. De resultaten lieten een hoge mate van consensus zien. De deelnemers waren het erover eens dat Nederlandse ziekenhuizen op dit moment niet systematisch aan externe eisen voldoen en dat de infrastructuur voor externe eisen in Nederlandse ziekenhuizen beter geregeld moet worden. Deelnemers gaven aan dat externe eisen efficiënter kunnen worden aangepakt en dat daardoor de naleving verbeterd kan worden, als de verwachtingen nauwkeuriger worden omschreven. Uit de studie blijkt dat het samenwerken aan de database met andere ziekenhuizen nuttig kan zijn en dat regelmatige uitwisseling tussen ziekenhuizen wenselijk is om hoge prioriteiten en nationale ontwikkelingen te bespreken. De database en het risico gebaseerde prioriteringssysteem zijn toepasbare en bruikbare hulpmiddelen om met de hoeveelheid externe eisen om te gaan. De respondenten geven aan dat ze deze tools ook in de toekomst gaan gebruiken.

Op basis van de resultaten beschreven in **hoofdstuk 3** hebben we middels een survey onderzocht hoe de ziekenhuisbestuurders omgaan met het handhaven van richtlijnen. De resultaten van de survey studie staan beschreven in **hoofdstuk 4**. Een vragenlijst werd in 2015 naar 116 Nederlandse ziekenhuizen gestuurd. Negenendertig responses werden opgenomen in de studie voor verdere analyse (netto respons van 36%). Alle gegevens, behalve de open vragen, werden met behulp van beschrijvende statistiek geanalyseerd in SPSS. Uit de resultaten blijkt hoe het ziekenhuisbestuur van de algemene en opleidingsziekenhuizen de verantwoordelijkheden voor de naleving van richtlijnen in hun organisaties hebben geregeld, hoe raden van bestuur omgaan met richtlijnen voor medisch specialisten en welke mogelijkheden er zijn voor verbeteringen. Ondanks het feit dat deelnemers vinden dat het belangrijk is richtlijnen na te leven ervaren deelnemers problemen ermee. De mate van naleving van richtlijnen werd vaak als laag gerapporteerd door meerdere belemmeringen voor de implementatie van richtlijnen. De bevindingen van de survey laten zien dat de verdeling van verantwoordelijkheden ten aanzien van de implementatie van richtlijnen problematisch is. Ziekenhuisbestuurders zijn verantwoordelijk voor de naleving van alle kwaliteitsnormen, de deelnemers ervaren echter het regelen van verantwoordelijkheden voor het naleven van externe eisen binnen

hun organisatie als een uitdaging. De deelnemers gaven aan verschillende informatiebronnen te gebruiken om op de hoogte te blijven van de status van de implementatie van richtlijnen voor medische specialisten, meestal door externe visitaties en interne audits. Terwijl bijna alle deelnemers verklaarden dat het belangrijk is dat ziekenhuizen zich houden aan de richtlijnen voor medische specialisten, zegt slechts 42% dat dit haalbaar is. Uit de studie blijkt dat er meerdere verbeteringsmogelijkheden zijn, zoals een nationale database met alle actuele richtlijnen, van waaruit veranderingen en nieuws direct naar ziekenhuizen en andere belanghebbenden gecommuniceerd wordt. Deze studie leidde tot aanbevelingen voor een verschuiving in de verdeling van verantwoordelijkheid, met minder verantwoordelijkheid voor de raad van bestuur en meer voor de medische specialist.

Uit de resultaten van **hoofdstuk 4** bleek dat veel ziekenhuizen problemen ervaren met de implementatie van richtlijnen in hun ziekenhuizen. We hebben besloten diepte interviews te voeren met drie van de ziekenhuizen die rapporteerden geen problemen te hebben, om te leren hoe deze ziekenhuizen ervoor zorgen dat richtlijnen in de praktijk worden gebruikt en om belangrijke boodschappen te identificeren voor andere ziekenhuizen.

Analyse van de interviews resulteerde in een aantal thema's met betrekking tot de implementatie van richtlijnen in ziekenhuizen, namelijk: samenwerking, inzet, ziekenhuisgrootte, nut van richtlijnen, intrinsieke motivatie en belemmeringen voor de handhaving van richtlijnen. Respondenten gaven aan dat de samenwerking tussen medisch personeel en het ziekenhuisbestuur van belang is om richtlijnen te implementeren. Respondenten rapporteerden dat de omvang van het ziekenhuis relevant is. Volgens hen is de implementatie eenvoudiger in kleinere ziekenhuizen. Als richtlijnen belemmerend werken of niet direct van toepassing zijn in hun ziekenhuis, dan zorgden respondenten ervoor dat de eisen op de juiste wijze afgestemd worden met intern beleid. Ondanks hun inzet en het zoeken naar het doel achter de regel hebben alle ziekenhuizen aangegeven moeite te hebben om alle richtlijnen toe te passen. De respondenten van de ziekenhuizen vonden richtlijnen nodig en nuttig en ze hebben de mogelijkheid om de implementatie te verbeteren, mits het ziekenhuisbestuur en medisch personeel toegewijd

zijn, intrinsiek gemotiveerd zijn, samenwerken en richtlijnen pragmatisch gebruiken. Als de middelen schaars zijn worden richtlijnen geprioriteerd. De ziekenhuizen, die problemen ondervinden met de implementatie van richtlijnen, legden eerder de nadruk op de externe verwachtingen en dat leidde tot defensief gedrag. De ziekenhuizen, die geen problemen met de implementatie ondervonden, waren meer gericht op het integreren van richtlijnen in hun eigen beleid.

In **hoofdstukken 2 tot en met 5** was de focus op de verantwoordelijkheden voor richtlijnen vanuit het oogpunt van ziekenhuisbestuurders: de vragen die we stelden waren gericht op welke problemen ziekenhuizen ervaren, hoe ze hun verantwoordelijkheden voor richtlijnen ervaren, hoe ze kennis nemen van wat van hun verwacht wordt, hoe ze in taken van hun organisatie investeren? Nu wilden we onze focus verbreden door niet alleen binnen de ziekenhuizen te kijken, maar ook naar de hele keten van ontwikkelen, implementeren en handhaven.

In **hoofdstuk 6** beschrijven we de resultaten van focusgroepgesprekken en presenteren we mogelijke strategieën voor ziekenhuizen en hun belanghebbenden met betrekking tot het gebruik van richtlijnen. Tijdens de focusgroepgesprekken wilden we mogelijke strategieën identificeren die de gehele keten van ontwikkeling, gebruik en handhaving van richtlijnen en normen in ogenschouw nemen en die het ziekenhuisbestuur en management zouden kunnen helpen om te gaan met normen en richtlijnen. Daarom hebben we een kwalitatieve studie uitgevoerd met drie focusgroepgesprekken met in totaal 28 deelnemers. Drie thema's kwamen voort uit de resultaten en toonden aan dat richtlijnmakers, handhavers van richtlijnen en richtlijngebruikers de problemen van ziekenhuisbestuurders met betrekking tot het monitoren en implementeren van richtlijnen herkennen. Diverse concrete oplossingen werden voorgesteld, zoals: duidelijke omschrijving van de taakverdeling in richtlijnen, duidelijkheid over het doel van de aanbevelingen, een maximum aantal kwaliteitsindicatoren voor ziekenhuizen en de implementatie van een goede infrastructuur voor informatietechnologie (IT). Samenvattend laten de resultaten van de focusgroepen zien dat ziekenhuizen samen moeten optrekken om een actieve speler te worden in het proces van richtlijnontwikkeling. Wij concluderen dat alle relevante belanghebbenden een

inspanningen moeten leveren om de keten van richtlijnontwikkeling, gebruik en handhaving in de gezondheidszorg te optimaliseren. Deelnemers waren ervan overtuigd dat de implementatie niet alleen de verantwoordelijkheid is van raden van bestuur en professionals.

Hoofdstuk 7 beschrijft dilemma's die we in de studies van **hoofdstuk 2 tot en met 5** tegenkwamen, waarin we de problemen met betrekking tot de implementatie van richtlijnen identificeren vanuit het perspectief van ziekenhuizen. Gedecentraliseerde richtlijnontwikkeling kan de acceptatie vergroten maar het bewustzijn belemmeren. Richtlijnen kunnen de standaardisatie van zorg op het gebied van specifieke ziektes vergemakkelijken, maar kunnen de standaardisatie op het ziekenhuisniveau belemmeren. Richtlijnen kunnen het leveren van maatwerk aan patiënten belemmeren als ze rigide toegepast worden. Richtlijnen worden vaak vanuit een deontologisch oogpunt ontwikkeld, waarbij professionals zich richten op de beste zorg voor de individuele patiënt. Daarbij houden ze niet per se rekening met het beste resultaat voor alle (ziekenhuis) patiënten. Echter, richtlijnen moeten worden geïmplementeerd in een utilitaire omgeving, waarbij eindige middelen op de beste mogelijke manier gebruikt moeten worden. Richtlijnontwikkelaars moeten deze rationaliteit niet uit het oog verliezen, maar gebruikers van richtlijnen helpen door de relevantie van de verschillende aanbevelingen te duiden. De resultaten lieten zien dat de handhaving ziekenhuizen moet helpen zich proactief op de meest relevante kwaliteitskwesties te richten. We concludeerden dat we moeten terugkeren naar het oorspronkelijke doel van richtlijnen (om de evidence based keuze de makkelijke keuze te maken) en pleiten voor een terugkeer naar een model waarin richtlijnen in wezen worden gebruikt voor leren (formatieve beoordelingen) in plaats van controle, beloning en straffen (summatieve beoordelingen).

In **hoofdstuk 8** vatten we de bevindingen van het proefschrift samen en reflecteren we op de literatuur. De resultaten van dit onderzoek laten zien dat de volledige naleving van richtlijnen door ziekenhuisbestuurders een "mission impossible" is. De realisatie dat ziekenhuizen verschillende uitdagingen ondervinden terwijl ze tegemoet komen aan richtlijnen en externe eisen, draagt ertoe bij te begrijpen dat de naleving van richtlijnen niet het uiteindelijke doel is. Het uiteindelijke doel is kwaliteit en veiligheid in de

ziekenhuiszorg, met relevante zorguitkomsten voor de patiënt. Om met de complexiteit van de implementatie van richtlijnen om te kunnen gaan, moet de nadruk liggen op verbeteren en leren. Onderzoek is nodig om te achterhalen of IT-oplossingen en “knowledge brokering” het gebruik van richtlijnen kunnen verbeteren. De resultaten van het proefschrift dagen uit tot nadenken over de vraag of strikte handhaving in alle gevallen de juiste weg is. De resultaten suggereren dat de handhaving toegespitst moet worden op een aantal eisen, die alle belanghebbenden kennen en waarover zij het eens is. Aanvullend onderzoek is nodig waarbij wordt uitgegaan van het ziekenhuis eenheid van analyse en als setting waarin meerdere professionele richtlijnen tegelijkertijd geïmplementeerd moeten worden en waarin klinische richtlijnen in lijn moeten worden gebracht met andere externe eisen.

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About the Author



Louise Blume was born on 25th of August 1987 in Frankfurt, Germany. After graduation from high school (Frankfurt, Germany), she studied Health Science at the University of Maastricht, the Netherlands (specialisation in management and prevention). She spent her Erasmus exchange time

in Finland, Kuopio, where she focused on ethical and cultural multiplicity, intercultural interaction and public health issues. She finished her Bachelor in 2009. In 2010, Louise obtained a Master's degree in Health Economics, Policy and Management of Maastricht University. After an internship about access times in outpatient clinics at the quality & safety department in a Dutch hospital (Atrium Medical Center, later Zuyderland Medical Center), she started working there in 2010. As a policy officer, Louise was involved in setting up and coordinated the integrated audit system of the hospital. She was one of the founders of the database l'artis and established it in the hospital. To share this innovation, Louise published together with Nico van Weert and Hans Kerckamp an article in Medisch Contact. After it became clear that coping with guidelines and other external demands is challenging for boards of directors of hospital, a research proposal was set up, which was granted by the NVZ and has led to the research presented in this thesis. In October 2013, Louise started her PhD under the supervision of Diana Delnoij, Nico van Weert and Jamiu Busari, next to working part-time in the Dutch hospital. She took a sabbatical year from summer 2014 to summer of 2015, to travel the world with her husband, Nino Schön. In August 2017, she started working for the Netherlands Federation of University Medical Centres. Louise volunteers for foodsharing e.V., is a hockey player and loves travelling.

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Presentations

- Presentation “Aansluiting van externe eisen op de praktijk in Nederlandse ziekenhuizen” for the Advisory and Expert Group Quality Standards (AQUA) on invitation. Zeist, Netherlands. 2017
- Presentation “Guideline adherence: How do boards of directors deal with it? A survey in Dutch hospitals” during the Guidelines International Conference (G-I-N conference) for international researchers. Philadelphia, USA. 2016.
- Presentation “Managing the Complexity of Care - What is the Role of Guidelines in Hospitals? A Survey in the Netherlands” at Scientific symposium at Zuyderland Medical Centrum, Heerlen, 2016.
- Brainstorm participant “Brainstormbijeenkomst Merkbaar minder regeldruk in MSZ” on invitation by the Ministry of Health, Welfare and Sport. Den Haag, 2016
- Presentation “Making hospitals responsible for guideline implementation: mission impossible?” during the Guidelines International Conference (G-I-N conference) for international researchers. Amsterdam, 2015.
- Presentation “ Externe Anforderungen an niederländische Krankenhäuser ” for the German Hospital Foundation (Deutsche Krankenhaus Gesellschaft), Amsterdam, 2014
- Presentation “Externe eisen voor Nederlandse ziekenhuizen: l’artis & prioriteringen” during Round Table discussion Dutch Hospital Association & Zuyderland Medical Center. Utrecht, 2014
- Presentation “Bewust omgaan met externe eisen in ziekenhuizen” at 8min4you. Heerlen, 2014.
- Presentation “Bijdrage Atrium MC aan bijeenkomst systeemtoezicht, IGZ 27 maart 2013” at Invitational Conference Systeemtoezicht from the Healthcare Inspectorate (IGZ). Utrecht, 2013.
- Presentation “Atrium MC - richtlijnen” for researchers during Quaser en DUQuE conference at iBMG. Rotterdam, 2013.
- Poster “Process audits” at European Care Pathway Conference. Amsterdam, 2012.

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